Subject Matter Code: C-13 Risk Level

Comment ID: CTR-003-003
Comment Author: City of Riverside
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: 3) We do not agree with the use of the 10'-6 risk level proposed here. As is noted in the proposed rule, a significant uncertainty factor ranging from 10 to 10,000 is used to set human health criteria. We can understand the use of these factors but the public should understand that they may be paying to protect to the 10'-10 or one in ten billion risk level. We suggest that the risk level used be tied to the certainty of risk. For example, where uncertainty factors range from 1 - 10, use 10E-6; 11 - 100, 10E-5 101 - 10,000, 10E-4 risk level. Another option would be to promulgate a range from which the permit writer may choose depending on the site specific nature of the waters and the needs of the effected individuals. At a minimum the EPA should promulgate at a factor of 10E-5 and allow the regional boards to set more stringent criteria if warranted. We all need to keep in mind that lower limits mean higher costs and higher costs here mean fewer resources available elsewhere. Even with the best of intentions, we may be sacrificing hundreds in an attempt to save one. For example, an increase in sewer rates reduces the discretionary money normally used for the purchase of food and medical services with potentially significant impacts on the poor.

Response to: CTR-003-003

See also response to Comment CTR-058-001.

The comment author suggests that the rule provide variable risk levels dependent on the uncertainty factor used in calculating national criteria guidance. It is suggested that higher risk levels be allowed for parameters having criteria based on a higher uncertainty factor. This suggestion runs counter to EPA policy that greater protection be provided when uncertainty concerning the adequacy of protection is greatest.

This author also suggests giving individual permit writers the authority/responsibility to choose the risk level on a site specific basis for each permit. This approach, along with the above suggestion, would result in risk levels that vary both on a parameter specific basis and a site specific basis. This approach may result in selective inadequate protection for highly exposed populations and even for the general population. EPA would support, in this case, an approach that includes scientifically valid site-specific criteria.

If the State has a scientific basis, and wants to adopt more or less protective site-specific criteria, it is within the State's discretion to do so (See response to CTR-058-001), but this rule is a reasonable attempt to protect all of California's waters.

EPA cannot respond specifically to the author's assertion of higher costs for sewer ratepayers because it

is provided without supporting evidence. EPA's Economic Analysis indicates that a change in the risk level from 10-5 to 10-6 would cause only a negligible increase in compliance costs for the State as a whole based on a sample of California facilities (Economic Analysis of the California Toxics Rule, P. A-2). Due to limited resources, EPA was not able to estimate potential costs for every facility in the State. In any case, water quality criteria must be based on that which is necessary to protect human health and the environment and must be scientifically based. Under, the Clean Water Act, this requirement overrides consideration of economic impacts.

Comment ID: CTR-005-007
Comment Author: Novato Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES

Comment: 6. Human health criteria for carcinogens should be adopted at a 10E-5 risk level. Based on the analyses performed by other Bay Area POT\ft, the District is concerned that organics monitoring of its effluent will identify human health criteria that cannot be achieved without dilution well beyond 1 0: 1 (e.g., aldrin, PAHS, heptachlor). At a 10E-6 risk level, the District would be forced to add activated carbon at a significant cost or possibly go to land disposal at an enormous cost. The benefits would be nil because the District is such a small contributor to the Bay and generally, according to the results of the Regional Monitoring Program, these criteria are not exceeded in the Bay.

Response to: CTR-005-007

EPA disagrees with this comment.

The comment author suggests that the rule should provide for a higher allowable risk level because monitoring indicates that current effluent concentration for certain pollutants exceed the levels provided at a risk level of 10-6 leading to enormous treatment/disposal costs. In the first place, the comment author has not provided specific data or evidence that shows any additional treatment will be needed. Secondly, EPA cannot justify reducingprotection to California's population across the State based on an assertion of a need for additional treatment and consequent added costs. Other federal and State processes such as site-specific criteria that lessen the need for pollutant removal and TMDLs that shift the need for pollutant load removal to other sources of that pollutant may be scientifically justified and could facilitate moving toward less costly treatment alternatives, should additional treatment be indicated; however, it is essential that beneficial uses remain fully protected.

In addition, the commentor notes that the criteria are not exceeded in the Bay. The State permit authority must show that the discharge of organics have reasonable potential to cause or contribute to an exceedence of water quality criteria in order to establish effluent limits. If no reasonable potential is established, the facility will not incur any costs for the control of organics.

Comment ID: CTR-011-001a
Comment Author: City of Simi Valley
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-011 incorporates by reference letters CTR-027 and CTR-034
Attachments? Y
CROSS REFERENCES C-24
E-01d

Comment: The City of Simi Valley discharges approximately 10 million gallons per day (mgd) of tertiarytreated wastewater (as well as municipal storm water) to the Arroyo Simi, an effluent dependent water body. Through much of the year, Arroyo Simi is dry several miles downstream from the City. The Arroyo Simi Characterization Report, completed by the City in 1995, concluded that the arroyo does not support a significant fishery, and observed only arroyo chub, mosquito fish and blunt-nosed minnow in the stream. Although designated as a potential municipal water supply in the Basin Plan, the arroyo waters are not used for municipal purposes. Effluent monitoring are limited, but available data indicate that the City's discharge may have a reasonable potential to exceed the proposed aquatic life criteria for several metals and the proposed human health criteria for several carcinogens.

Since Simi Valley is largely a residential community with supporting commercial development and little industry, and since the City already has an effective pretreatment program, it is unlikely that pollution prevention efforts would effectively reduce the problematic constituents. More likely, the City would be faced with end-of-pipe treatment controls such as lime precipitation and carbon adsorption to achieve the proposed criteria. The costs would undoubtedly be significant and the benefits relatively minor.

Under these circumstances, it appears reasonable to adopt criteria for Arroyo Simi, and similar effluent dependent waters, that are reasonably achievable without costly end-of-pipe controls and that reflect the actual use of the water (i.e., generally such waters are used for fishing or drinking). One way to address this issue, consistent with the requirements of the Clean Water Act, would be to adopt specific human health criteria for Arroyo Simi and other effluent dependent streams based on a cancer risk coefficient of 10E-5 or in some cases 10E-4. Based on the limited data collected by the City, risk levels of 10E-4 would have to be adopted for dioxins, aldrin, alpha-BHC and 4,4,-DDD (see Table 1). Risk levels of 10E-5 would be sufficient for chloroform and endoslfan 11 (Id.).

Response to: CTR-011-001a

EPA disagrees with this comment.

See also responses to CTR-058-001 and CTR-005-007.

When EPA promulgates a rule, it follows national policy and what it understands to be the policy of the state in selecting a risk level for the general population. (See response to comment CTR-058-001) EPA would not use a higher general risk level for specific pollutants unless it had data showing that consumption of those pollutants is less than the general consumption levels EPA uses along with the general risk level of 10-6.

The commenter suggests determining criteria by assessing what the condition of the effluent is, without assuming application of what it deems as costly controls, by applying a different risk level for various pollutants for the same waterbody. In other words, the commenter proposed that site specific human health criteria be adopted for their receiving water based on individual pollutant effluent data. Site specific criteria are the prerogative of the State and are generically recognized in this rule; however, effluent data cannot serve as sufficient justification for criteria.

The State could remove a use designation pursuant to its own regulations as long as it is not an existing use. Justification for the use removal or replacement would need to be developed as provided for in 40 CFR Part 131. This action would require a Use Attainability Analysis and would need to assure that full protection of existing uses and other designated beneficial uses of the waterbody is provided.

EPA cannot respond specifically to the commentor's assertion that it would incur costs for end-of-pipe costs for sewer ratepayers because it is provided without supporting data. EPA's Economic Analysis indicates that a change in the risk level from 10-5 to 10-6 would cause only a negligible increase in compliance costs for the State as a whole based on a sampling of facilities (Economic Analysis of the California Toxics Rule, P. A-2). Due to limited resources, EPA was not able to estimate potential costs for every facility in the State. In any case, water quality criteria must be based on that which is necessary to protect human health and the environment and must be scientifically based. Under, the Clean Water Act, this requirement overrides consideration of economic impacts.

Comment ID: CTR-015-002
Comment Author: Eastern Municipal Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: Cancer Risk Level (FR p.42181, Preamble section E.3.f.)

The Agency requests comment on the adoption of a 10E-5 risk level for carcinogenic pollutants rather than a 10E-6 risk level. The Agency should be aware of an analysis conducted by the State Water Resources Control Board ("State Board") as part of the Functional Equivalent Document, or environmental impact review, for the Inland Surface Waters Plan in March, 1992. The analysis compared inland discharger's ability to attain objectives at both risk levels. Effluent data from 23 inland dischargers for the period of 1989 to 1991 were used. Thirty-nine constituents (mostly organic compounds) were examined. Although the State Board selected the 10E-6 level, differences in attainability were shown and described.

In the Agency's Economic Analysis of July, 1997 for this Rule, there was a comparison of costs between the two risk levels in Section 4. It is stated on p. 4-17 that there was a lack of data for organic pollutants and, for those facilities with data, most of these pollutants were found below detection limits. It is not certain, then, how many constituents were examined for the risk level economic analysis. Also, fewer dischargers were examined by the Agency than by the State Board in its previous studies. However, in

Section 10 (p. 10-2), it was concluded by the Agency that there were minimal cost differences between the two risk levels.

Obviously, the 10E-5 risk level would be more attainable and less costly than the 10E-6 risk level. It is probable, from our review so far, that the Agency has underestimated the cost differences. A more thorough cost/benefit analysis, i.e., a comparison done at a greater level of detail such as the State Board had done for attainability, is needed for the Agency's Rule before a risk level is suggested or adopted.

Response to: CTR-015-002

EPA disagrees with this comment.

See response to CTR-058-001.

In regard to the comment about the results of the economic analysis which compared the potential costs of a 10-5 and 10-6 risk level, EPA believes that its methodology is sound. EPA examined recent monitoring data for eachsample facility. The fact that some facilities have a lack of data or that many of the organic pollutants that were monitored were measured below the detection limit does not necessarily mean that these facilities would not be able to comply with WQBELs based on a 10-6 risk level Even if facilities expand monitoring efforts or if detection limits are improved, the commenter has provided no evidence that compliance costs would significantly increase. EPA included as many sample facilities it could to project statewide costs taking into account time and resource constraints.

Comment ID: CTR-021-005a
Comment Author: LeBoeuf, Lamb, Green & MacRae
Document Type: Local Government
State of Origin: CA
Represented Org: City of Sunnyvale
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-021 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES C-28
E-01c
R
S

Comment: It is with a sense of reluctance that Sunnyvale joins in CASA/Tri-TAC's adverse comments ont eh CTR and teh EA, and Sunnyvale does so in a spirit of constructive criticism and with an expectation that the Agency will make the necessary adjustments in its approach towards the CTR before the final rule is promulgated. In addition, in the same spirit and with the same expectation, Sunnyvale would like to make the following points on its own behalf:

2. Obligation to Assess Alternative Cancer Risk Levels for Human Health-Based Criteria. Sunnyvale is gravely concerned that EPA has used the wrong approach in proposing to establish human health criteria for organic pollutants, particularly those pollutants for which the proposed criteria are below the method level of detection ("MDL"). Sunnyvale recommends that EPA should thoroughly assess all of the potential impacts, including costs and benefits, of the 10E-4 and 10E-5 risk levels before proposing the

human health-based criteria. As pointed out in the EOA Letter, there is a significant potential for advancing technology to lower the MDL for many pollutants to the point where laboratory equipment is able to measure some or all of the organic compounds for which EPA is proposing to establish criteria at the new level. It is intuitively obvious that the costs of attaining criteria set at the 10E-6 level will be significantly greater than attainment of a 10E-5 or 10E-4 level, particularly where, as pointed out in the EOA Letter, the only available method of treatment is granular activated carbon. Sunnyvale is concerned that the EA does not adequately address the potential for these costs, and, consequently, does not take these potential costs into account in determining whether to exercise its flexibility in choosing whether to use a 10-4 , 10-5 or 10-6 cancer risk level as the basis for its CTR promulgation.

EPA is required by Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act to identify and analyze alternatives to a proposed rule. We cannot understand, therefore, why EPA has done such a cursory analysis in the preamble to the CTR and the EA of the alternatives to the use of the most stringent (10E-6) risk level for establishing criteria for human health effects of pollutants, particularly organic pollutants. EPA cannot base its selection of the 10E-6 level based upon previous regulatory pronouncements by the State of California. Any new determination by the State will be subject to the analytical requirements of Section 13241 of the Porter-Cologne Act and by review by the Office of Administrative Law. Thus, it is not a foregone conclusion that the State will ultimately select the 10E-6 level. EPA has its own legal requirements to fulfill. Accordingly, we ask that EPA not promulgate the final human health criteria for the pollutants of concern unless and until it has adequately analyzed the costs and other implications of the various alternatives to the 10E-6 level.

In conclusion, we are entirely supportive of many of EPA's inovative approaches towards development of the CTR, particularly as regards the toxic metals. However, we believe that EPA has needlessly failed to comply with many of its legal obligations, particularly as regards the development of human health-based criteria on cancer risk levels of organic pollutants. We urge the Agency to reconsider its position in the matters covered by this letter (as amplified by the EOA Letter) and the CASA/Tri-TAC letter. Sunnyvale pledges its continued participation in place-based watershed management planning in the South Bay, its cooperation with the Agency in making a success of the WPI, and to an ongoing effort by the Agency and others to reach water quality goals in the South Bay. We thank you for the opportunity to comment on the proposed CTR.

Response to: CTR-021-005a

EPA disagrees with this comment.

See response to Comment CTR-058-001 and CTR-011-001a.

In regard to the comment about the results of the economic analysis which compared the potential costs of a 10-5 and 10-6 risk level, EPA believes that its methodology is sound. The fact that many of the organic pollutants that were monitored were measured below the detection limit does not necessarily mean that these facilities would not be able to comply with WQBELs based on a 10-6 risk level. Even if detection limits are improved, compliance could not be determined until the results of using the new monitoring method was completed.

Comment ID: CTR-035-004
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.

State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: [INDENT]- EPA should select human health criteria for carcinogens based on the 10E-5 or 10E-4 risk levels instead of the 10E-6 level. This approach would be consistent with other EPA regulatory actions such as the Great Lakes Initiative for which EPA used the 10E-5 risk level in setting the criteria, or the national drinking water program where maximum contaminant levels are commonly developed with a risk level of 10E-4 to 10E-5. Moreover, EPA should acknowledge that there is considerable uncertainty and variability in the risk assessment process. The criteria are calculated using a model that assumes low dose linearity. When using this kind of model, the calculation of risk to several significant figures at any given low dose gives the illusion of knowledge and precision that are not really there. Thus, the actual risk to the exposed population associated with a risk level of 10E-4 may be virtually indistinguishable from a risk level of 10E-6, yet the socioeconomic impacts associated with complying with criteria promulgated using the 10E-6 risk level can be significant. Thus, EPA should reconsider the risk level used in calculating criteria in the CTR and should select a lower risk level.

Response to: CTR-035-004

EPA disagrees with this comment.

See response to CTR-058-001.

The fact that maximum contaminant levels in the drinking water program are sometimes developed with a risk level in the range of 10-4 to 10-5 is not a factor in setting ambient water quality criteria. Under the Safe Drinking Water Act, MCLs are set taking best available technology into account, while under the Clean Water Act, water quality criteria are set solely based on human health or aquatic protection.

Comment ID: CTR-035-021
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: pp. 42175-42176 -- Reference Doses (RfDs) For non-carcinogenic human health criteria, EPA divides a "no observed effect" dose in animal studies by an uncertainty factor, which ranges from 10 to 10,000 based on various factors such as whether the data are being extrapolated from animals to humans. In addition, a modifying factor greater than 0 and less than 1O is applied to reflect the professional judgment of toxicologists. The use of such large uncertainty factors indicates that there is a large margin

of safety in the criteria, and some flexibility in the application of these factors. We recommend that EPA consider using this flexibility, for instance, to develop criteria appropriate to effluent dependent waters. In many cases, little or no fish consumption occurs and no direct use of the water for drinking water supplies may occur in effluent dependent waters; therefore the risk of human exposure is small, and it would be appropriate to use lower uncertainty and modifying factors in promulgating criteria for these water bodies.

Response to: CTR-035-021

EPA disagrees with this comment.

See response to CTR-058-001.

The comment author recommends that EPA develop criteria appropriate to effluent dependent waters. In the CTR, EPA has applied criteria on the basis of State adopted beneficial uses. As the State has not used a beneficial use category that distinguishes effluent dependent waters, there are no waters to assign a separate set of criteria. The CTR does not preclude the State from developing a special beneficial use category for effluent dependent waters should it choose that course of action. (See EPA Region 9's Interim Final "Guidance for Modifying Water Quality Standards and Protecting Effluent-Dependent Ecosystems", June 17, 1992, for guidance.)

Comment ID: CTR-035-027
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42181 -- Risk Factors for Carcinogens EPA has calculated the human health criteria for carcinogens in the proposed CTR using a 10E-6 risk level, but invites comment on whether the criteria for carcinogens should instead be calculated using a risk level of 10E-5. We recommend that EPA consider a range of risk levels between 10E-4 and 10E-6, which we understand to be consistent with EPA's policy of allowing States to use risk levels in the range of 10E-4 to 10E-6 when adopting criteria for carcinogenic priority pollutants in water quality standards (U.S., EPA, 1994b). We do not agree with EPA's proposition to adopt a 10E-6 risk level based upon previous regulatory decisions by the State. Any new determination by the State will be subject to the legal requirements of Section 13241 of the Porter-Cologne Act and by review by the Office of Administrative Law. Thus, it is not a foregone conclusion that the State will ultimately select the 10E-6 level. Moreover, EPA should acknowledge that there is considerable uncertainty and variability in the risk assessment process. The criteria are calculated using a model that assumes low dose linearity. When using this kind of model, the calculation of risk to several significant figures at any given low dose gives the illusion of knowledge and precision that are not really there. Thus, the actual risk to the exposed population associated with a risk level of 10E-4 may be virtually indistinguishable from a risk level of 10E-6, yet the socioeconomic impacts associated with complying with criteria promulgated using the 10E-6 risk level can be significant. EPA

should therefore revise its alternative analysis for the 10E-5 risk level evaluated for the cost analysis, and reassess its conclusions. We believe this re-analysis to be necessary for EPA to adequately comply with the requirements of Executive Order 12866, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act to identify and analyze alternatives to a proposed rule.

Response to: CTR-035-027

EPA disagrees with this comment.

See response to CTR-058-001. In that response EPA explained that protection of the general population at the 10-6 risk level was necessary to assure that those segments of the California population that are more highly exposed are protected at a 10-4 risk level.

EPA is unable to respond to the generic comment that "...the actual risk to the exposed population associated with a risk level of 10E-4 may be virtually indistinguishable from a risk level of 10E-6,..." when using a linear cancer risk model. The commenter has provided no supporting evidence for this assertion.

Comment ID: CTR-040-015b
Comment Author: County of Sacramento Water Div
Document Type: Storm Water Auth.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-040 incorporates by reference letter CTR-027
Attachments? Y
CROSS REFERENCES S

Comment: RECOMMENDED MODIFICATIONS

To address our concerns, we recommend the following modifications which do not undermine the toxic pollutant control actions envisioned in EPA's economic analysis (e.g., BMPs for stormwater and source control). In fact, some of these recommendations would provide incentives for greater movement toward achieving the water quality criteria than would occur under the Rule as it is currently proposed.

II. Recommendation: Adopt human health criteria for PAHs at a 10 (-4) risk level and human health criteria for other carcinogens at risk levels that are generally achieved by municipal wastewater and stormwater dischargers.

* As previously stated, the Sacramento Stormwater Management Program would have to expend on the order of $260 million per year to treat stormwater, and this may not achieve the proposed criteria for PAHS, which is based on a 10 (-6) cancer risk level.

* Under the Unfunded Mandates Reform Act, EPA must adopt the least cost alternative for complying with the CWA, unless the Administrator explains in the final rule why the least cost alternative is not adopted. As indicated in the Preamble, risk levels of 10 (-5) and 10 (-4) are acceptable under the CWA.

* Therefore, pursuant to the spirit of the Unfunded Mandates Reform Act, EPA should adopt the PAH criteria at a 10 (-4) risk level. The same should be true for other carcinogens that present attainability problems for dischargers. Most carcinogenic constituents are not readily controllable through source control or BMPs and would generally require end-of-pipe controls to achieve significant reduction. The benefits associated with additional reduction of carcinogenic constituents are not expected to be measurable since, as acknowledged in the economic analysis,point sources are relatively minor sources of these constituents.

Response to: CTR-040-015b

See responses to CTR-058-001 and 011-001a.

Concerning comments CTR-043-006b and CTR-044-007a, the statements that neither Old Alamo Creek nor Tule Canal are "heavily fished" is not relevant to the health issue, i.e., are the people who do fish highly exposed because they are high consumers? The commentors have not provided sufficient information to evaluate either question.

The comment that the carcinogens that are asserted to be compliance problems for these two dischargers are not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California may merely reflect a lack of information on these pollutants in sample locations that were selected for the benefits analysis. The fact that no baseline risks were found for the purposes of the analysis does not mean that the risk from these pollutants do not exist anywhere in California or should not be prevented.

Comment ID: CTR-043-006b
Comment Author: City of Vacaville
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES C-24

Comment: 6. EPA should adopt separate, site-specific human health criteria for Old Alamo Creek based on a 10 (-4) risk level. As previously indicated the City would have to construct costly end-of-pipe controls to comply with the human health criteria for several carcinogens. The subject criteria are based on a cancer risk level of 10 (-6). These controls would not produce a commensurate environmental benefit. At a 10 (-4) risk level, the City's discharge would not cause an in-stream exceedance of these criteria. The City does not believe Old Alamo Creek is heavily fished and therefore criteria based on a 10 (-4) risk level would likely provide greater protection than indicated by the risk level. The City notes that none of these carcinogens were identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California (see Exhibit 8-9 in EPA's economic analysis).

Response to: CTR-043-006b

See responses to CTR-058-001 and 011-001a.

Concerning comments CTR-043-006b and CTR-044-007a, the statements that neither Old Alamo Creek nor Tule Canal are "heavily fished" is not relevant to the health issue, i.e., are the people who do fish highly exposed because they are high consumers? The commentors have not provided sufficient information to evaluate either question.

The comment that the carcinogens that are asserted to be compliance problems for these two dischargers are not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California may merely reflect a lack of information on these pollutants in sample locations that were selected for the benefits analysis. The fact that no baseline risks were found for the purposes of the analysis does not mean that the risk from these pollutants do not exist anywhere in California or should not be prevented.

Comment ID: CTR-044-007a
Comment Author: City of Woodland
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES C-24

Comment: We have reviewed the proposed CTR and offer the following comments:

6. EPA should adopt separate, site-specific human health criteria for Tule Canal based on a 10 (-4) risk level. Based on effluent sampling, the City would have to construct costly end-of-pipe controls to comply with criteria for aldrin (and perhaps other carcinogens) based on a 10 (-6) risk level. These controls would not produce a commensurate environmental benefit. At a 10 (-4) risk level, the City's discharge would not cause an in-stream exceedance of these criteria in Tule Canal. The City does not believe Tule Canal is heavily fished and therefore criteria based on a 10 (-4) risk level would likely provide greater protection than indicated by the risk level. The City notes that aldrin was not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California (see Exhibit 8-9 in EPA's economic analysis).

Response to: CTR-044-007a

See responses to CTR-058-001 and 011-001a.

Concerning comments CTR-043-006b and CTR-044-007a, the statements that neither Old Alamo Creek nor Tule Canal are "heavily fished" is not relevant to the health issue, i.e., are the people who do fish highly exposed because they are high consumers? The commentors have not provided sufficient information to evaluate either question.

The comment that the carcinogens that are asserted to be compliance problems for these two dischargers

are not identified in EPA's economic analysis as a significant contributor to baseline cancer risks for recreational anglers consuming freshwater fish in California may merely reflect a lack of information on these pollutants in sample locations that were selected for the benefits analysis. The fact that no baseline risks were found for the purposes of the analysis does not mean that the risk from these pollutants do not exist anywhere in California or should not be prevented.

Comment ID: CTR-049-003
Comment Author: Watereuse Assoc. of California
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: With respect to other criteria proposed for adoption in the draft CTR, we recommend that USEPA:

1 . Adopt human health criteria for carcinogens which are based on the 10E-5 or 10E-4 risk levels instead of the 10E-6 level. (Based on all the conservative assumptions included in the calculation of the criteria, there is significant uncertainty in the numbers, which may translate to negligible risk in using the lower risk levels. This draft CTR should factor in this uncertainty into the risk assessment along with population exposure when calculating risk and appropriate human health criteria);

Response to: CTR-049-003

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-050-006
Comment Author: Sonnenschein Nath & Rosenthal
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org: American Petrol
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: III. The Acceptable Risk Level Should be greater than 10E-6.

EPA has proposed that the criteria for carcinogens should be based on an acceptable risk level of 10E-6.

However, the Agency has also, at the request of the State of California, requested comment on an alternative risk level of 1OE-5. (62 Fed. Reg. at 42181). The 10E-5 figure is recognized and utilized by EPA in various Clean Water Act guidance documents as well as in other Agency programs: Moreover, in the most comprehensive development and implementation of water quality standards that the Agency has ever conducted - the Great Lakes Initiative (GLI) -EPA used this risk level in setting the criteria. Also, every State in Region 5 has followed the EPA policy and used 10E-5 as the acceptable risk level in setting water quality standards as part of their GLI rules. EPA should continue that policy in this rulemaking.

Response to: CTR-050-006

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-052-003a
Comment Author: East Bay Dischargers Authority
Document Type: Sewer Authority
State of Origin: SC
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-052 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES E-01
E-02

Comment: However, the Authority is greatly disappointed that EPA chose not to follow the consensus recommendations for many of the most significant issues, including the methodology used for the EA and the choice of using the most conservative carcinogenicity factor for organic pollutants.

Response to: CTR-052-003a

EPA disagrees with this comment.

See response to CTR-058-001.

The risk level chosen for the CTR is not "the most conservative carcinogenicity factor for organic pollutants."

Comment ID: CTR-054-007
Comment Author: Bay Area Dischargers Assoc.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level

References:
Attachments? Y
CROSS REFERENCES

Comment: Human health criteria for carcinogens should be adopted at a 10 (-5) risk level at least for San Francisco Bay waters. BADA's attainability analyses shows that adoption of criteria for carcinogens based on a 10 (-6) risk level would result in significant costs without improving the present level of compliance in Bay waters. At a 10 (-6) risk level, two BADA agencies could be faced with adding carbon adsorption facilities at a total annual costs of $56 million per year (to achieve effluent limitations for aldrin, heptachlor and several PAHS). At a 10 (-5) risk level, carbon adsorption facilities would be unnecessary at these BADA agency plants. The cost savings would be significant, and the present high level of compliance would remain unchanged.

Response to: CTR-054-007

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-055-001
Comment Author: USS-POSCO Industries
Document Type: Specific Industry
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES

Comment: UPI requests the EPA use a Cancer Risk Level at 10E-5 (1 in 100,000) in the subject regulation.

The U.S. Environmental Protection Agency (EPA) and the State of California (State) have requested comment on the adoption of a 1OE-5 carcinogenic risk factor (page 42181) in lieu of the proposed 10E-6 factor. The EPA criteria documents for priority toxic pollutants do not recommend a specific carcinogenic risk factor, but rather a range of risk factors is recommended. The EPA is proposing a California rule that meets Clean Water Act (CWA) section 304(a) minimum. Since a 10E-5 carcinogenic risk factor meets CWA criteria as determined by the EPA, a 10E-5 carcinogenic risk factor is appropriate for the subject Section 131.38. The State should have the authority to use a 10E-5 carcinogenic level. The State needs the option of developing regulatory standards to protect the people and the environment in California in a manner which considers local conditions within the state.

For the above reasons, UPI requests the EPA promulgate a 10E-5 carcinogenic risk factor (1 in 100,000) in the subject regulation.

Response to: CTR-055-001

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-056-012
Comment Author: East Bay Municipal Util. Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-056 incorporates by reference letter CTR-054
Attachments? N
CROSS REFERENCES

Comment: Third, regarding the criteria being proposed for adoption in the draft CTR, EBMUD recommends that EPA should:

* Select human health criteria for carcinogens based on the 10E-5 or more appropriate risk level instead of the 10E-6 level being proposed. Based upon the conservative risk assumptions included in the calculation of criteria, there is sufficient uncertainty in the numbers to permit the use of a less restrictive value than 10E-6. EBMUD believes that by using the "one in a million" risk assumption an undue attainability burden is being placed on dischargers to meet ultra-low water quality criteria for very little gain in risk reduction. EPA should factor the uncertainty of the numbers into the risk assessment along with the population exposure when calculating risk and appropriate human health criteria.

Response to: CTR-056-012

EPA disagrees with this comment.

See response to CTR-058-001. For an additional response, see also the response to CTR-003-003.

Comment ID: CTR-057-005
Comment Author: City of Los Angeles
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: Risk Level

The EPA is strongly encouraged to consider the use of the 10E-5 carcinogenic human health risk

criterion as a baseline for all priority-pollutant criteria that can be adjusted as appropriate when conditions merit a change. The 10E-6 criterion, which itself already appears to serve as such a baseline, is too problematic for this purpose in view of the number of priority constituents which represent immediate compliance problems under the proposed Rule. The attached tables compare our chances for compliance with the proposed Rule under the two factors for our three facilities. We believe that the problems associated with the 10E-6 factor primarily reflect a difficulty with criteria compliance rather than an indication of environmental impact.

In addition, we believe that cost-benefit ratios of mitigation efforts based on a 10E-5 risk factor are considerably more justifiable than 10E-6 in view of the diminishing returns most POTWs would experience in terms of net environmental cost-benefit. For example, years of toxicity testing of Tillman effluent has not established any relationship between effluent lindane and/or DDT levels and aquatic survivability, yet further reduction of these pollutants below currently-observed levels does not justify the enormous required treatment costs. By comparison, the cost effectiveness of best-management practices for non-point sources is attractive, but the trade-off in terms of immediate benefit is a significant limitation- These observations imply that the 10E-5 risk factor should also be applicable on a constituent-specific basis, and we urge the EPA to consider this application as well.

Another factor to consider in setting the risk criterion involves pollutant source-controllability. For example, DDT is a banned pesticide that is ubiquitous in the environment and also a pass-through pollutant in conventional treatment processes what purpose does a 10E-6 factor serve when it cannot be controlled by either point or non-point sources? If treated, where and how are the wastes disposed? The provenance and ultimate fate of such pollutants should be considered as part of a more holistic approach to their control, and the establishment of overly-stringent risk criteria does not accomplish that.

Response to: CTR-057-005

EPA disagrees with this comment.

See response to CTR-058-001.

The comment author cites "years of toxicity testing of Tillman effluent" as evidence that effluent levels of lindane and/or DDT do not need to be further reduced . However, this comment overlooks the fact that these two pollutants are highly bioaccumulative, and standard toxicity tests, because of their short duration, do not account for most bioaccumulation. Thus, if anything, a 10-6 risk level is particularly appropriate for bioaccumulative pollutants.

EPA disagrees that a factor to consider in setting of risk criterion should involve pollutant source controllability. First, the commenter has provided no evidence supporting the assertion that either point or nonpoint sources cannot be controlled. EPA also disagrees that it should set criteria for pollutants that are difficult to control (which have been banned but remain persistent in the environment) at a higher risk level than other pollutants. The Clean Water Act requires that criteria be protective of designated uses. While EPA has discretion in setting risk levels appropriate to protect uses, EPA believes that it is appropriate to base the risk level on nationally appropriate risk levels and the risk level established by the State for the general population. (See the response to Comment CTR-058-001.) By doing so, EPA will be providing an acceptable measure of protection to all exposed subpopulations. If it is not feasible to attain a designated use due to human caused conditions or if sources of pollution prevent the attainment of the use and cannot be remedied, EPA regulations allow the State to remove the designated use if it is not an existing use. This approach allows for regulatory relief where attainment is infeasible while avoiding the lowering of water quality protection to people who live in areas where it may be feasible to

attain the criteria at a risk level of 10-6.

Comment ID: CTR-058-001
Comment Author: Western States Petroleum Assoc
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? Y
CROSS REFERENCES

Comment: We appreciate the care that EPA has given to this proposal and especially the attempt to base the proposal on good science. Although there are significant improvements in the proposal, there are several issues of concern to WSPA. We are especially concerned that EPA has chosen to base the proposal on a human health risk level of 1x10E-6 while other environmental management programs administered by EPA or by California regulatory agencies have based decisions on risk levels of 1x10E-5 and above. EPA has not justified this overly cautious and potentially expensive approach. Our comments are included in the attachment to this letter.

1. Acceptable Risk Levels. WSPA opposes use of a 1x10E-6 risk level as a trigger level for regulatory action.

EPA has historically considered health risks above 1x10E-6 to be adequately protective of human health (see, e.g., 40 CFR 42176 in this rulemaking and review articles by Travis et al., Environ. Science Tech. 21(5): 415-420, 1987 and Rodricks et al., Toxicol. Pharmacol. 7: 307-320, 1987). Yet, "EPA is proposing criteria that protect at an incremental cancer risk level of one in a million (1x10E-6) for all priority toxic pollutants regulated as carcinogens" [62 FR 42181, subpart f]. EPA apparently bases this decision on what it believes to be the state's historical policy, although adequate justification for the target risk level selected is not provided.

EPA is overlooking an overwhelming consensus of state and national-level policy which indicates that, in reality a target risk level of 1x10E-6 is not commonly applied in developing regulatory levels. For example, in the most comprehensive rulemaking on development and implementation of water quality standards that EPA has ever conducted -- the Great Lakes Initiative -- EPA used a target risk level of 1x10E-5 in setting the criteria. Also, every state in Region V has followed EPA policy and used 1x10E-5 as the acceptable risk level in setting water quality standards as part of their GLI rules.

EPA's National Contingency Plan codifies 1x10E-4 to 1x10E-6 as the target acceptable risk range for evaluating hazardous waste sites under CERCLA. EPA has selected and promulgated a single risk level of 1x10E-5 in the Hazardous Waste Management System Toxicity Characteristics Revisions [55FR 11798-11863]. In so doing, EPA notes that "The chosen risk level of 10E-5 is at the midpoint of the reference risk range for carcinogens (10E-4 to 10E-6) generally used to evaluate CERCLA actions.". EPNs benzene waste NESHAPs used 10E-5 and drinking water MCLs are commonly associated with acceptable risk levels that exceed 1x10E-6. OSHA's recently proposed procedures for developing risk-based Permissible Exposure Limits (PELs) are based on acceptable risk levels of 1x10E-3 to 1x10E-4.

In California, state agencies commonly rely on target risk levels above 1x10E-6 for setting regulatory action levels. Cal-EPA, including the DTSC, the SWRCB and the RWQCBs routinely set cleanup levels for remediation projects based on a target risk of 1x10E-5 The air quality management districts charged with administering the California Air Toxics "Hot Spots" Program under AB2588 commonly rely on a 1x10E-5 target risk level for risk management purposes. California's proposed revision to the hazardous waste classification system is also similarly based on a 1x10E-5 risk level. California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) established a no significant risk level of 1x10E-5 for evaluating potential exposures of the general population to carcinogenic chemicals.

Reliance on a single target risk level of 1x10E-6 for setting water quality criteria is now mostly an historical artifact. In reality, even when the Food and Drug Administration originally proposed that a 1x10E-6 target risk level be used to set safety standards in the 1970s, this level was clearly meant to be a de minimis level representing risks that are so small as to be of negligible concern. In the interest of responsible public policy, EPA's target risk level should reflect an enlightened understanding of the uncertainty and variability inherent in the risk assessment process gained since that time. In addition, given that the background cancer risk in the U.S. is now about 30%, EPA should recognize that a risk level of 0.30001, or for that matter 0.3001, is virtually indistinguishable from a risk level of 0.300001. By contrast, the socioeconomic impacts associated with the overly conservative reliance on a 1x10E-6 risk level could be staggering.

Response to: CTR-058-001

EPA disagrees with this comment.

EPA's section 304(a) criteria guidance documents for priority toxic pollutants that are based on carcinogenicity present concentrations for upper bound risk levels of 1 excess cancer per 100,000 people (10-5), per 1,000,000 people (10-6), and per 10,000,000 people (10-7). However, the criteria documents do not recommend a particular risk level as EPA policy. EPA uses a 10-6 risk level in establishing human health criteria guidance because it believes that a 10-6 risk level is an appropriate level of risk for the general population. This risk level is used by a majority of states and Tribes.

Subpopulations within a state may exist, such as subsistence anglers who as a result of greater exposure to a contaminant, are at greater risk than the assumed 70 kilogram person eating 6.5 grams per day of maximally contaminated fish and shellfish and drinking 2.0 liters per day of drinking water with pollutant levels meeting the water quality criteria.

When EPA promulgates criteria as regulations, EPA generally follows the policies of the affected state. In this case, California has articulated a policy choice of 10-6 for the general population. By establishing rules at the 10-6 risk level, EPA applies a risk management policy which ensures protection for all exposed population groups (Draft Water Quality Criteria Methodology: Human Health, EPA 822-Z-98-001,August 1998, Appendix II, page 72). EPA acknowledges that at any given risk level for the general population, those segments of the population that are more highly exposed face a higher relative risk. For example, if fish are contaminated at a level permitted by criteria derived on the basis of a risk level of 10-6, individuals consuming up to 10 times the assumed fish consumption rate would still be protected at a 10-5 risk level. Similarly individuals consuming 100 times the general population rate would be protected at a 10-4 risk level. EPA therefore believes that protection at the 10-6 risk level is a reasonable risk management decision protective of designated uses under the CWA. While outside the scope of this rule, EPA notes that states and Tribes, however, have the discretion to adopt water quality criteria that result in a higher risk level (e.g., 10-5). EPA expects to approve such criteria if the state or

Tribe has identified the most highly exposed subpopulation within the state or Tribe, demonstrates the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation.

This demonstration has not happened in California. Further, the information that is available on highly exposed subpopulations in California supports the need to protect the general population at the 10-6 level. California has cited the Santa Monica Bay Seafood Consumption Study as providing the best available dataset for estimating consumption of sport fish and shellfish in California for either marine or freshwater sources (Chemicals in Fish Report No. 1: Consumption of Fish and Shellfish in California and the United States, Final Draft Report, July 1997). Consumption rates of 21g/day, 50 g/day,107 g/day, and 161 g/day for the median, mean, 90th, and 95th percentile rates, respectively, were determined from this study. Additional consumption of commercial species in the range of approximately 8 to 42 g/day would further increase those values. Clearly the consumption rates for the most highly exposed subpopulation within the State exceeds 10 times the 6.5 g/day rates used in the CTR. Therefore, use of a risk level of 10-5 to protect the general population would not be sufficient to protect the most highly exposed population in California at a 10-4 risk level. On the other hand, even the most highly exposed subpopulations cited in the California study do not have consumption rates approaching 100 times the 6.5 g/day rate used in the CTR. The use of the 10-6 risk level to protect median level consumers does not subject these subpopulations to risk levels as high as 10-4.

EPA believes it would be reasonable to conclude that carcinogens that bioaccumulate, particularly given the exposure of fishermen to such carcinogens, may justify site-specific criteria that result in more protective risk level than 10-6 for the average fish consumer. EPA has generally supported such decisions when adequate data are available. In this rulemaking, EPA has adopted a reasonable risk level to protect all of California's inland waters and enclosed bays and estuaries for consumption of fish and drinking water.

EPA believes its decision to establish a 10-6 risk level for the CTR is also consistent with EPA's policy in the NTR and GLI to select the risk level that reflect the policies or preferences of Clean Water Act programs in the affected states. CA adopted standards for priority toxic pollutants for its ocean waters in 1990 using a 10-6 risk level to protect human health (California Ocean Plan, 1990). In April 1991, and again in November 1992, CA adopted standards for its inland waters and enclosed bays and estuaries in its ISWP and EBEP using a 1x10-6 risk level. To be consistent with CA's WQS, EPA used a 10-6 risk level for CA in the NTR at 57 FR 60867/3. CA has continued using a 10-6 risk level to protect human health for its standards that were not withdrawn with the ISWP and EBEP. The most recent expression of risk level preference is contained in the Draft Functional Equivalent Document, Amendment of the Water Quality Control Plan for Ocean Waters of California, October 1998, where staff recommended maintaining a consistent risk level of 10-6 for the human health standards that they were proposing to revise. See also the discussion in responses to CTR-002-002a and CTR-002-005a.

The citation of programs that occasionally allow a risk level as high as 10-4 under specific circumstances does not prove to be inconsistent with protection of the general population at the 10-6 level recognizing that more highly exposed sub-populations such as ethnic or economically disadvantaged populations may face an excess risk level approaching 10-4.

There are several differences between the guidelines for the derivation of human health criteria contained in the Great Lakes Water Quality Guidance (the Guidance) and the California Toxics Rule (CTR) that make a 10-5 risk factor appropriate for the Guidance, but not for the CTR. These differences result in criteria developed using the 10-5 risk factor in the Guidance being at least as stringent as criteria derived under the CTR using a 10-6 risk factor. The relevant aspects of the Guidance include:

* targeting of sensitive subgroups of the population, such as people who routinely eat fish caught in the Great Lakes, in assessing risk (the CTR targets the population in general)

* use of fish consumption rates that are considerably higher (because of the targeted subgroup) than fish consumption rates for the CTR

* use of bioaccumulation factors rather than bioconcentration factors in estimating exposure, considerably increasing the dose of carcinogens to sensitive subgroups

* use of additivity of effects of mixtures of both carcinogenic and noncarcinogenic pollutants.

This combination of factors increase the calculated carcinogenic risk substantially under the Guidance (the combination would generally be more than one order of magnitude), making a lower overall risk factor acceptable. The Guidance risk factor provides, in fact, criteria with at least the same level of protection against carcinogens as criteria derived with a higher risk factor using the CTR. A lower risk factor for the CTR would not be appropriate absent concomitant changes in the derivation procedures that provide equivalent risk protection.

Remediation efforts and OSHA PELs were cited by the comment author as activities allowing risk levels higher than 10-6. These activities are site-specific and have far less impact beyond a very local area as contrasted to WQS which, in combination with existing California WQS providing protection of the general population at the 10-6 level, will provide consistent protection to the statewide population. [See the reference to HHM Notice above].

EPA disagrees that reliance on a 10-6 target risk level for setting water quality criteria is now mostly a historical artifact. The Food Quality Protection Act of 1996 (FQPA) amended the Federal Food, Drug, and Cosmetic Act to prohibit EPA from issuing tolerances for pesticide residues in or on food unless the agency determined that there is "reasonable certainty" that the residues will result in "no harm." The legislative history of FQPA indicated Congressional support for EPA's view that reasonable certainty of no harm would be met when a non-threshold risk is below a 10-6 level.

EPA believes that comparing the "background cancer risk in the U.S." (an aggregate risk combining the effect of all causes of cancer) with the excess cancer risk from a single toxic pollutant in water is not appropriate because they are not comparable measures. The comment author's argument does not lend support for raising the risk level specified in this rulemaking. The purpose of the CWA is to protect waters (in this case for the various human uses) irrespective of the cancer risk derived from other sources.

Finally, EPA is unable to respond to the author's assertion of "staggering" socioeconomic impacts because it is provided without supporting evidence (see response to CTR-005-007). EPA's Economic Analysis indicates that lowering the risk level from 10-5 to 10-6 would cause only a negligible increase in compliance costs (Economic Analysis of the California Toxics Rule, p. A-2). In any case, under the Clean Water Act, EPA must establish scientifically based criteria that protect designated uses. This requirement overrides any consideration of socioeconomic impacts. The Clean Water Act does allow consideration of socioeconomic impacts in decisions to remove a designated use which is not an existing use.

Comment ID: CTR-060-016
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

* Health risk factor - The preamble to the rule (see 62 Fed. Reg. at 42,181, Col. 3) states that the cancer risk level used to calculate the criteria is 1 excess cancer case per 1,000,000 people. The State of California voters approved an initiative in 1986 "The Safe Drinking Water andToxic Enforcement Act of 1986" ("Prop. 65") to address concerns over exposures to toxic chemicals. Prop. 65 defines the "no significant risk" level as follows:

"For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question,...".(*15)

The criteria proposed in the rule should be recalculated to reflect a one excess case of cancer in an exposed population of 100,000 risk factor, which would be consistent with an existing risk factor which is acceptable to the voters in the State of California.

(*15) Subsection 12703 (b) at CCR Title 22, Division 2, Part 2, Subdivision 1, Chapter 3, Article 7.

Response to: CTR-060-016

EPA disagrees with these comments.

See response to CTR-058-001.

Comment ID: CTR-066-011
Comment Author: Delta Diablo Sanitation Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: The areas with which we find concerns and the requested changes include the following:

* With respect to the criteria proposed for adoption in the draft CTR, we believe EPA should select human health criteria for carcinogens based on the 10E-5 or 10E-4 risk levels instead of the 10E-6 level. Based on all the conservative assumptions embedded in the calculation of the criteria, there is significant uncertainty in the numbers, which may translate to negligible risk in using the lower risk levels. EPA should factor this uncertainty into the risk assessment along with population exposure when calculating risk and appropriate human health criteria.

Response to: CTR-066-011

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-081-003
Comment Author: West County Agency
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: * EPA should select human health criteria on levels other than the 10E-6 level, based on the conservative assumptions included in the calculation of the criteria.

Response to: CTR-081-003

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-082-004
Comment Author: City of Burbank
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: The subject rule has a significant impact on our facility discharge and the citizens of the City. We therefore present the following comments for your consideration to re-open the comment period for this rule in order to facilitate a more complete review by public and in particular by those in the POTW community:

* Recommend USEPA use human health criteria for carcinogens based on the 10(*-5) or 10(*-4) instead of the 10(*-6) level. It is important to note that all conservative assumptions included in the calculation of the EPA proposed criteria there is a significant uncertainty in the numbers, which may translate to negligible risk in using the lower risk levels. EPA should factor in this uncertainty into the risk amount along with population exposure when calculating risk and appropriate human factor.

Response to: CTR-082-004

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-085-013
Comment Author: Camarillo Sanitary District
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: The District supports the following positions of CASA and SCAP where changes need to be made in the proposed California Toxics Rule:

* With respect to the criteria proposed for adoption in the draft California Toxics Rule, the EPA should select human health criteria for carcinogens based on the 10E-5 or 10E-4 risk level instead of the 10E-6 level. Based on all the conservative assumptions included in the calculations of the criteria, there is significant uncertainty in the number, witch may translate to negligible risk in using the lower risk levels. The EPA should factor this uncertainty into the risk assessment, along with population exposure, when calculating risk and appropriate human health criteria.

Response to: CTR-085-013

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-090-013

Comment Author: C&C of SF, Public Utl. Commis.
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-090 incorporates by reference letters CTR-035 and CTR-054
Attachments? Y
CROSS REFERENCES

Comment: 2. The Cancer Potency Risk Factor Should Be 10E-5 EPA should not assume that 10E-6 is California's preferred risk level for estuarine and inland surface waters. The action adopting that risk level was invalidated by the courts specifically on the grounds that the SWRCB did not follow the required procedures of the Water Code section 13241. In fact, the State of California and the voters of California have made a clear policy statement about cancer risk factors when they enacted in 1986, the Safe Drinking Water and Toxic Enforcement Act, known as Proposition 65. This Proposition established significant restrictions on the use of toxicants based on a cancer risk level of 10E-5. This voter approved cancer risk is far more valid and should be the guide to the EPA for the criteria.

The use of the 10E-6 as a risk level for human health will cause some constituents to be to considered problem pollutants when in fact no problem exists based on site specific data and bioaccumulation data. This high level of risk compounds the very conservative assumptions and other safety factors already within the formula for the criteria.

We urge the EPA to revise the cancer risk level to 10-5. Until such time that a source of problem toxicants are better identified, interim CRFs of less than 10E-5 would be appropriate for some carcinogens (more discussion in the detailed comments)

Response to: CTR-090-013

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-092-015
Comment Author: City of San Jose, California
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-13 Risk Level
References: Letter CTR-092 incorporates by reference letter CTR-035
Attachments? Y
CROSS REFERENCES

Comment: We want to highlight our technical concern with one aspect of the Economic analysis in the text of this letter - EPA's proposal to protect at an incremental cancer risk level of one in one million (10E-6) for all priority toxic pollutants regulated as carcinogens. The CTR states that "EPA recommends

that states consider minimum risk levels in the range of 10E-4 to 10E-6 for carcinogenic priority pollutants to protect public health and welfare." The City supports EPA's policy of allowing States the flexibility to use a range of cancer risk levels in their derivation ofcriteria for carcinogenic priority pollutants, however the City believes that the EPA has the same obligation in promulgating the CTR. The City recommends that risk levels be determined dependent upon the degree of scientific uncertainty inherent with the appropriate criterion. Stringency of risk levels should be established based upon the degree of significance, that assumptions and uncertainties drive the criterion derivation process.

Response to: CTR-092-015

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTR-096-008
Comment Author: City of Modesto
Document Type: Local Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: Thank you for the opportunity to comment on the proposed California Toxics Rule. The City's comments are related to five main concepts:

Specifically, the City submits he following comments:

G. Further, with respect to the criteria proposed in the draft CTR, EPA should select human health criteria for carcinogens based on 10E-5 or 10E-4 risk levels instead of the 10E-6 level. Based on all the conservative assumptions included in the calculation of the criteria, there is significant uncertainty in the numbers, which may translate to negligible risk in using the lower risk levels. EPA should factor this uncertainty into the risk assessment along with population exposure when calculating risk and appropriate human health criteria.

Response to: CTR-096-008

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTRH-001-026
Comment Author: Michelle Pla
Document Type: Public Hearing
State of Origin: CA

Represented Org: S.F. Public Utilities Com
Document Date: 09/17/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: In your proposed rule you said that 10 to the minus 6 is the appropriate cancer risk factor, but you're asking for comments on the 10 to the minus -- to the -- 10 to the minus 5. And I would like to point out that although the state originally in their guidelines for effluents had 10 to the minus 6, that was one of the grounds for the court case which overthrew that, those plans, in that they did not do a thorough analysis. The 10 to the minus 6, we will be giving you more information in written comments why we believe that 10 to the minus 5 is an appropriate risk level.

Response to: CTRH-001-026

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTRH-001-046
Comment Author: Charles Batts
Document Type: Public Hearing
State of Origin: CA
Represented Org: Bay Area Dischargers Assc
Document Date: 09/17/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: We would ask you to review scientific carcinogenic criteria with concern for special pathways that disclose how carcinogenics in aquatic runoff and wastewater interact with human health.

Presently the risk factor of 10 to the minus 6 is heaped on an already overly conservative criteria. The use of 10 to the minus 4 or 10 to the minus 5 have been incorporated by EPA in many other risk analysis plans that they've done, including the Safe Drinking Water Act and the Great Lakes Initiative,

Also in this area, greater study should be done to look at individual organic compounds to see what the cost/benefit ratio is and see if there is a way for removal of these specific organic compounds by source control or pollution prevention techniques.

Response to: CTRH-001-046

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTRH-002-013
Comment Author: Lisa Ohlund
Document Type: Public Hearing
State of Origin: CA
Represented Org: Alliance of So. CA POTWs
Document Date: 09/18/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: We'd like to see the EPA reexamine risk level for carcinogens in the human health criteria, taking into consideration the actual change in risk to the exposed population for each constituent and balancing that with the potential cost of compliance.

Response to: CTRH-002-013

EPA disagrees with this comment.

See response to CTR-058-001.

Comment ID: CTRH-002-023
Comment Author: John Behjan
Document Type: Public Hearing
State of Origin: CA
Represented Org: City of Simi Valley
Document Date: 09/19/97
Subject Matter Code: C-13 Risk Level
References:
Attachments? N
CROSS REFERENCES

Comment: MR. BEHJAN: Good afternoon. My name is John Behjan, B-e-h-j-a-n. My business address is 500 West Los Angeles Avenue, Simi Valley, California 93065.

Basically, I want to go over the CTR's proposed numerical objective for human health risk -- human health criteria which is based on human health risk assessment of 10(-6). That is basically for the cases that are consumable water for fish.

The previous speaker mentioned about waterways and this is where I'm coming from. We recommend EPA's consideration of another factor than the 10(-6). EPA does provide that, the flexibility. And this is a very appropriate application, perhaps in for -- because that would reduce the objectives more -- make them more difficult than for a lot of fish in Southern California who are discharging it into water.

Thank you.

Response to: CTRH-002-023

EPA disagrees with this comment.

See response to CTR-058-001.

Subject Matter Code: C-14 Fish or Water Consumption

Comment ID: CTR-002-002a
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? Y
CROSS REFERENCES C-17a

Comment: I. TOXIC POLLUTANTS THREATEN PUBLIC HEALTH AND SAN FRANCISCO BAY.

Toxic pollution causes harm in San Francisco Bay. Species of bivalve shellfish, plankton and phytoplankton that are especially vulnerable to toxic trace elements such as copper are decimated in its southern reach though they thrive in comparable estuaries with less metals pollution.(*1) (*2) Mounting evidence suggests its sediment is toxic to some aquatic life.(*3) Extensive research strongly suggests that PCBs and PAHs released to the Bay negatively effect reproduction in starry flounder. (*4) Reproductive effects are also correlated with PCBs in Bay cormorant eggs, Bay harbor seals have PCBs levels twice those associated with immunotoxicity and a disease epidemic that decimated a European population of this species.(*5) Health advisories are in effect because dioxin, PCBS, mercury, chlordane, DDT, dieldrin, and selenium contaminate Bay food resources eaten by the public.(*6) (*7)

Public health threats from toxics in the food chain are of particular concern. A recent count found approximately 270,000 fishing licenses were issued to Bay Area residents. Surveys by CBESAFER!, the Save San Francisco Bay Association, and the Asian Pacific Environmental Network show that many people fish the Bay regularly to supplement their families' diet, that some people eat up to a maximum of a pound of fish per day, and that the majority of those who eat their catch regularly are people of color. [See attachment (*8)] A pound of fish per day is about 480 oz./month, sixty times the 8 oz./month "safety" cutoff for cancer and slow learning in the state's advisory.(*6)

In addition to these severe environmental health and justice problems, pollutant monitoring of the Bay is far from comprehensive, and undetected problems are likely. Indeed, EPA acknowledged that designated uses of the Bay are threatened or impaired by toxic pollutants when it named the Bay as a "toxic hot spot" under Section 304(l) of the Clean Water Act.(*9)

(*1) U.S. Geological Survey, 1992. Letter from Samuel N. Luoma, Ph.D., to Seven R. Ritchie, Executive Officer, Regional Water Quality Control Board. August 24, 1992.

(*2) Karras, 1992. Comparison of copper in waters of the southern reach of San Francisco Bay and ten other estuaries. Communities for a Better Environment (CBE). July, 1992.

(*3) San Francisco Estuary Institute, 1997. Regional monitoring program for trace substances 1995 annual report. Excerpts including pages 105, 3, and A-17 through A-24 showing the percentage of sediment bioassays (larval bivalve and Eohaustorius tests) that were toxic (less than 80% of control

value) at RMP stations from 1991-1996, sampling stations, and dissolved and total metal, and PAH concentrations in San Francisco Bay waters.

(*4) Spies et al., (2 papers), 1988: Effects of organic contaminants on reproduction of the starry flounder Platichthys stellatus in San Francisco Bay, I., Hepatic contamination and mixed-function oxidase (MFO) activity during the reproductive season. Marine Biology 98: 181-189; and II. Reproductive success of fish captured in San Francisco Bay and spawned in the laboratory. Marine Biology 98: 191-200. Excerpt including abstracts.

(*5) Kopec and Harvey, 1995, Toxic pollutants, health indices, and population dynamics of harbor seals in San Francisco Bay, 1989-1992. Moss Landing Marine Laboratories Technical Publication 96-4. ISSN 1088-2413. October, 1995. Excerpt regarding PCBs levels as compared to European seals in which a disease epidemic and population crash was observed.

(*6) Cal. EPA, 1994. Health advisory on catching and eating fish, interim sport fish advisory for San Francisco Bay. December, 1994.

(*7) California Department of Health Services, 1994. Health Warnings, Contained in the 1994 California Hunting Regulations for Resident and Migratory Game Birds issues by the state's Fish and Game Conunission, Sacramento, Calif. Excerpt including health warning for selenium.

(*8) Previously unpublished data froma 1993-4 survey of 500 anglers using South and Central San Francisco Bay by conununities for a Better Environment-SAFER!; Save San Francisco Bay Association, 1995 (excerpt); West, 1992; West et al., 1992; Peterson et al., 1994; and USEPA, 1994.(excerpt of a draft report discussing and citing work by EPA, Wolfe and Walker (1987), Svensson (1991) and others. Includes analysis of the evidence..

(*9) EPA, 1990. Decision of the United States Environmental Protection Agency on listing under section 304(l) of the Clean Water Act regarding the state of California. Excerpt including pages listing San Francisco Bay waters as a "toxic hot spot."

Response to: CTR-002-002a

See response to CTR-001-002.

EPA acknowledges the impacts of pollution in the San Francisco Bay. EPA believes that the intake rate of 6.5 grams/day is adequately protective of the general population of fish consumers over the course of a lifetime. The fish intake rate of 6.5 gm/day is from a national, 30-day survey - the National Purchase Diary (NPD), based on an empirical distribution, where 6.5 gm/day represents the average value for the general population. According to the NPD, which was based on over 25,000 individual respondents, 94 percent of the survey respondents reported that they ate fish. Therefore, EPA believes that 6.5 gm/day is an appropriate basis for characterizing the general population. EPA understands that fish intake patterns vary and that there are population groups that consume significantly greater amounts than the overall population.

For this regulation, the promulgated criteria were derived using a 10-6 risk level, which the Agency believes reflects an appropriate risk for the general population and ensures protection for all exposed population groups. EPA also considers that the goal is satisfied if the general population will be adequately protected by human health criteria when the criteria are met in ambient water. EPA acknowledges that at any given risk level for the general population, those segments of the population

that are more highly exposed face a higher relative risk. For example, if fish are contaminated at a level permitted by criteria derived on the basis of a risk level of 10-6, individuals consuming up to 10 times the assumed fish consumption rate would be protected at a 10-5 risk level. Similarly, individuals consuming up to 100 times the assumed rate would still be protected at a 10-4 risk level. Consistent with this, a criterion based on 6.5 gm/day at a risk level of 10-6 would protect those who consumed 650 gm/day at a 10-4 risk level.

EPA has advocated State and Tribal flexibility to develop criteria, on a site-specific basis, that provides additional protection appropriate for highly exposed populations. EPA has not found that such a demonstration has been made for specific waterbodies covered by the CTR that warrants a change or re-proposal of the CTR criteria at this time. EPA understands that highly exposed populations may be widely distributed geographically throughout a given State and Tribal area. Thus, if the State or Tribe determines that a highly exposed population would not be adequately protected by criteria based on the general population, EPA recommends that the State/Tribe adopt more stringent criteria. Furthermore, EPA recommends that States and Tribes ensure that the most highly exposed populations not exceed a risk level of 10-4.

It should also be understood when comparing the fish intake assumption of 6.5 grams/day used to develop these criteria with other studies, including the studies referenced by the commenter (such as the surveys by "CBESAFER!", the Save San Francisco Bay Association, etc.), that the 6.5 gm/day value reflects consumption of fresh/estuarine species only and does not include marine species. It is the fresh/estuarine species that apply to the development of water quality criteria for the waters covered under this rule. Specifically, the CTR's ambient water quality criteria are applicable to inland waters and estuaries. The CTR does not apply to ocean waters that are covered by California's Ocean Plan. The commenter needs to separate out marine species before any comparisons between studies can be appropriately made. EPA's water quality criteria program policy has historically been to evaluate fish intake from fresh and estuarine species only, based on knowledge of life-cycles of the species including relevant information from the National Marine Fisheries Service. The purpose is to include those species that are anticipated to be potentially exposed to pollutants in fresh and estuarine waterbodies, based on this life-cycle information [for further discussion on this policy, see the Ambient Water Quality Criteria Derivation Methodology Human Health Technical Support Document, Final Draft (EPA-822-B-98-005)].

EPA is developing a revised methodology for deriving water quality criteria to protect human health and is updating its recommendations for estimating fish consumption, including evaluating the most recent survey data (see draft revisions published August 14, 1998, Federal Register, Vol. 63, No. 157). EPA is currently reviewing public comments and is awaiting the results of a peer review on the draft methodology revisions. However, until the methodology is finalized, EPA believes that the current methodology is scientifically defensible.

Comment ID: CTR-002-005a
Comment Author: Comm. for a Better Environment
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? Y

Comment: C. Criteria for the pollutants of most concern do not provide equal protection for people of color and are not supportable by science.

EPA cannot show that its weaker proposed criteria will protect fishing and aquatic life from dioxin-like compounds, mercury, and copper. Further, EPA's proposal to allow greater health risks for subsistence fishers fails to provide equal protection under the law and is contrary to the President's Executive Order on Environmental Justice.

The proposed criteria provide unequal protection for people of color who fish for food. EPA admits in the proposal that: "There may be subpopulations within a state, such as subsistence anglers who as a result of greater exposure to a contaminant, are at greater risk than the hypothetical 70 kilogram person eating 6.5 grams per day of maximally contaminated fish.. ." Indeed, ample data show that some people exercise their fishing rights to "use" Bay waters by eating up to a pound (450 grams) per day of fish from San Francisco Bay, and most of them are people of color.(*8) EPA's discussion then goes on to admit that it is proposing to provide less protection for these subsistence anglers: "[I]ndividuals that ingest ten times more of a carcinogenic pollutant than is assumed in derivation of the criteria at a [one excess cancer in a million] risk level will be protected to a [one in 100,000] level, which EPA has historically considered to be adequately protective." However, people who eat a pound per day eat seventy times more, and pages 8- 11 and 8-12 of EPA's economic analysis admit people eat 16 times more, than the 6.5 grams (1/70th of a pound) of Bay fish per day assumed in EPA's criteria. EPA's own calculations show present cancer threats of nearly 1 in 1,000 for some Bay anglers at these higher consumption levels. Thus, EPA itself predicts that its proposal will result in lesser, inadequate protection for people of color who rely on Bay-caught fish for food.

(*8) Previously unpublished data from a 1993-4 survey of 500 anglers using South and Central San Francisco Bay by Conununities for a Better Environment-SAFER!; Save San Francisco Bay Association, 1995 (excerpt); West, 1992; West et al., 1992; Peterson et al., 1994; and USEPA, 1994. (excerpt of a draft report discussing and citing work by EPA, Wolfe and Walker (1987), Svensson (1991) and others. Includes analysis of the evidence.

Response to: CTR-002-005a

EPA believes that this rule is consistent with the terms of the Executive Order (E.O.) on Environmental Justice. EPA rejects the notion that the rule is, in any respect, discriminatory against persons or populations because of their race, color, or national origin. The final rule establishes criteria that are designed to ensure protection of the public, including highly exposed populations. While some groups and individuals, including some low income and minority persons and populations, may face a greater risk of adverse health effects than the general population due to their particular fish consumption patterns, EPA believes that these groups will nonetheless receive a level of public health protection within the range that EPA has long considered to be appropriate in its environmental programs (e.g., 10-4 to 10-6 incremental cancer risk). Obviously, as long as there is variability in fish consumption patterns among various segments of the population, it would be impossible for EPA to ensure that all groups would face identical risk from consuming fish. Therefore, EPA has sought to ensure that, after attainment of water quality criteria in ambient waters, no group is subject to increase cancer risks greater than the risk range that the EPA has long considered protective. EPA disagrees that individuals who consume up to a pound of fish per day would face a 10-3 cancer risk. Given that the basis of the criteria

are a 6.5 gm/day assumption at a 10-6 risk level, individuals who consume a pound of fish per day would be protected within the established acceptable range of 10-4 to 10-6, consistent throughout current EPA program office guidance and regulatory actions. See also the discussion in response to CTR-002-002a.

Comment ID: CTR-006-002b
Comment Author: Natural Resources Defense Cncl
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/22/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? Y
CROSS REFERENCES C-01a

Comment: Dear Ms. Frankel,

The Natural Resources Defense Council strongly opposes the Region 9 EPA proposal to raise the allowable mercury criterion for continuous concentration in water from 0.012 parts per billion (ppb) to 0.770 ppb for aquatic life. This proposal is difficult to justify from the point of view of science and of public health. On behalf of our over 350,000 members nationwide and our over 55,000 California members, we are writing to register our opposition to the EPA proposed rule.

Mercury is a highly poisonous metal which results in toxicity to the brain and nervous system and toxicity to human reproduction. In addition, in sediments, mercury is bio-transformed into the even more toxic form, methyl mercury, which has resulted in some of the largest epidemics of neuro-developmental poisoning known to mankind. Methyl mercury bioaccumulates in the food chain and thereby results in greatly concentrated exposures to humans, because we eat off the top of the food chain. Underestimates of the toxicity and bioaccumulation of mercury have led to major mistakes in the past. The Minamata Bay disaster in Japan was caused by a failure to predict the potency of mercury and the extent of human exposure through fish. U.S. EPA's Draft Mercury Study Report to Congress documents that children of high-end fish consumers in the U.S. may be exposed to enough mercury to cause adverse neuro-developmental effects.

In this setting it is anomalous to relax the standards for mercury contamination in California water. Furthermore, the scientific reasoning behind the Region 9 EPA decision to relax the mercury standard 60-fold is fraught with errors. NRDC's major concerns with this approach are summarized below.

*Extrapolation for the Reference Dose (RfD) should start at a NOAEL, not at a level of 10% increased risk. *An additional 10-fold safety factor should be added in deriving the RfD to account for the vulnerability of fetuses, infants, and children. *The body weight in the calculation should be for a child, not an adult male. *The Fish consumption rates for those who do eat fish should be used instead of rates for the entire population including those who do not eat fish. *Average fish consumption quantities greatly understate the risk to those who eat a lot of fish. Instead, fish consumption for the top 5% of the population should be used. *Bioaccumulation is known to be 10 to 100 fold greater than the estimate used by EPA. *California's waters are already too polluted with mercury.

Use of Average Fish Consumption is not Health Protective

The assumption used by Region 9 EPA for fish consumption relies on the average fish and shellfish consumption in the entire general population, along with the average intake from each body of water. It is quite clear that fish consumption follows a highly skewed, or Poisson distribution in the population (see attachment from the U.S. EPA Draft Mercury Study Report to Congress, Appendix H, p. 20). Many people eat little or no fish, but a smaller, yet highly significant segment of the population eats a very large amount of fish. Surely EPA should strive just as hard to protect the health of those who eat fish frequently as it does to protect the health of those who do not eat fish.

In fact, this analysis adequately protects only those who eat little or no fish. The average whichwas used in the Region 9 EPA analysis appears to derive from the "per capita" data from the USDA Continuing Surveys of Food Intake by Individuals (CSF 11) from 1989-91 for males ages 15-44 years. (See attached tables from U.S. EPA Mercury, Report, Appendix H, pp. 8 & I 1). In fact, this average is highly influenced by those individuals who consume little or no fish. Non-fish-consumers, however, are not the population of interest for purposes of this analysis. Instead, if an average is to be used, it should be the average fish consumption rate for those people who do eat fish. This is substantially higher, at 53.7 g/day for males ages 15-44 years, and 41.4 g/day for females in the same age range. Furthermore, the average fish consumption will likely underestimate the fish consumption rate for the "high end" fish consumer by many orders of magnitude. For example, in the case of females ages 15-44 years, average fish consumption (among those who do eat fish) is 41.4 g/day, while fish consumption by the top 5% of the population of these women of childbearing age is about 112 g/day, or more than double the average consumption rate.

The implications of not adequately protecting the high fish consumer are not trivial. The population of California is nearly 30 million, of whom overall 31% would be expected to be fish consumers according to the CSF II survey. This represents over 9 million people who would be at disproportionate risk. The top 5% of that population consists of nearly half a million people in California who would be expected to eat fish at nearly 10-times greater quantity than the EPA calculations would predict. 10 times greater consumption would translate into roughly 10-times greater risk from the mercury in the fish. EPA is not adequately protecting this substantial portion of the California population from mercury hazards.

NRDC strongly urges Region 9 EPA to reassess the proposed standard for mercury. Recalculation of the reference dose to accommodate the known disproportionate impact of mercury on fetuses, infants, and children will require addition of at least another 10-fold safety factor. The starting point for RfD calculation should be a true NOAEL. The body weight calculation should use an average weight for a child. Fish consumption data should reflect the "high-end" consumer. Finally, the outdated and unsupportable bioaccumulation factor of 7300 should be discarded in favor of a BAF which is supported by the current science in California.

Response to: CTR-006-002b

Regarding the issues on mercury health effects, derivation of the RfD, and basis of the fish intake assumption (including discussion of the CSFII survey), see response to CTR-006-002a. For additonal discussion regarding the basis of the fish consumption rate, see the response to this issue in CTR-002-002a. Regarding the choice of body weight, see response to CTR-006-001a. Regarding the issues on bioaccumulation, see response to CTR-002-007b.

Comment ID: CTR-010-002

Comment Author: Save San Francisco Bay Assoc.
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/24/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? Y
CROSS REFERENCES

Comment: The Bay is already highly polluted, as is evidenced by the adverse impacts on beneficial uses, particularly fish consumption. The State's Bay Protection and Toxic Cleanup Program has identified numerous probable toxic hot spot locations in the San Francisco and Santa Monica Bays, and confirmed hot spots in San Diego Bay. As bad as San Francisco Bay water quality already is, EPA's Toxics Rule proposal will make current conditions seem pristine compared to what lays ahead if this proposal is enacted.

Response to: CTR-010-002

Regarding the site-specific contamination issues, see response to CTR-002-003.

Comment ID: CTR-015-001
Comment Author: Eastern Municipal Water Dist.
Document Type: Sewer Authority
State of Origin: CA
Represented Org:
Document Date: 09/23/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: Dear Ms. Frankel:

Eastern Municipal Water District ("District") provides potable and reclaimed water and sewer service to an area of 555 square miles in western Riverside County in Southern California. The District has five regional water reclamation facilities in Moreno Valley, Hemet/San Jacinto, Perris Valley, Temecula Valley and Sun City with a total available capacity of 49 million gallons per day. There are 77,000 fresh water customers and 122,000 sewer connections. The District has a National Pollutant Discharge Elimination System ("NPDES") permit to discharge effluent, which could be combined from all five facilities, to Temescal Creek in the Santa Ana River Basin.

Submitted herewith are comments from the District on the Proposed Rule referenced above, appearing in the August 5 Federal Register, also called the California Toxics Rule ("Rule") . Several District staff have participated in the State Water Quality Planning Process since 1990. It has been complicated and frustrating, especially in light of attempting to obtain NPDES permits while the state was developing plans. Generally, the District is pleased that your agency ("Agency") is bringing some closure to the

issue by promulgating criteria. We do have some recommendations and concerns, however, which we present for your consideration.

Human Health Criteria (FR p. 42178, Preamble section E.3.)

Regarding fish and shellfish consumption rates, which are an important factor in calculating these water quality criteria, the District supports the Agency's use of 6.5 grams/day. What is of concern is the Agency's statement, "EPA supports the State's use of any appropriate higher state-specific fish and shellfish consumption rates in its readoption of criteria in its statewide plans." The discussion centers on the adopted California Ocean Plan's use of 23 grams/day, which was based on a California Department of Health Services memorandum of 1989. It is important to note that this exposure value was based on ocean fish consumption, whereas the Agency's value is based on non-marine fish consumption.

If a high consumption rate is used, the water quality criterion is lower or more stringent. This would become an additional burden for inland dischargers such as our District. For inland waters, and for any developed inland surface water quality criteria, we would like the Agency to recognize that lower consumption rates could also be used. The following shows the mean consumption rates of fish which are representative of California freshwater fisheries. These rates were taken from the Agency's Exposure Factors Handbook of 1989.

Bluegills --O.089 grams/day Carp --O.016 grams/day Catfish --O.292 grams/day
Perch --O.062 grams/day Sunfish --O.020 grams/day Trout --O.294 grams/day

Generally, the District hopes that appropriate consumption rates are used and desires that site-specific studies be conducted before different rates are selected. We would like to summarize the Agency's own procedures for developing data upon which to base alternative consumption rates, from the Exposure Factors Handbook, 1989, p. 2-39:

1. Interview local recreational fishermen in the affected area and obtain actual consumption rates. Local surveys can provide the most accurate data for exposure assessment purposes.

2. Obtain productivity data for the area and divide total catch data by the number of recreational fishermen in the area.

3. Estimate what portion of fish consumed in the local area is caught in the local area. Apply the diet fraction to the 50th and 90th percentile consumption rates.

4. Develop exposure scenarios assuming a number of fish meals eaten in the area per year, applying a meal size in the range of 100 to 200 grams/meal.

The Agency should encourage the state to conduct, at a minimum, studies in the manner described above for the following situations: lakes and reservoirs, inland surface streams, effluent-dominated streams, and ephemeral and-intermittent streams.

Response to: CTR-015-001

EPA acknowledges the commenters support of the 6.5 gm/day fish intake assumption. EPA also generally agrees that the rate should be indicative of consumption of freshwater and estuarine species only (see additional discussion on the fish intake rate assumptions in response to CTR-002-002a). However, the commenter has expressed concern over the use of California's Ocean Plan fish consumption

rate as a potential "additional burden" for inland dischargers. The commenter appears to support this concern by providing six species-specific intake rates "representative of California freshwater fisheries." EPA believes that this comparison is not appropriate. First, the State of California has both an Inland Surface Waters Plan and an Enclosed Bays and Estuaries Plan that would be more relevant to inland dischargers. Second, the commenter has chosen only several species of fish from a much larger tabulated list in the original 1989 Exposure Factors Handbook (revised in 1995). The table presents consumption data from a study conducted approximately 20 years ago for fish consumers in the United States. EPA believes that this is not necessarily representative of California-specific consumption patterns. EPA has long supported the States' use of local site- or State-specific data over EPA's default values to better reflect the variability of local or regional consumption patterns, when adequate data are available. EPA has published guidance on how to conduct such surveys. The Agency's most recent document is Guidance for Conducting Fish and Wildlife Consumption Surveys (EPA-823-B-98-007).

Comment ID: CTR-026-007a
Comment Author: Cal. Department of Fish & Game
Document Type: State Government
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: 7. HUMAN HEALTH CRITERIA

As you are aware the Department of Fish and Game is the trustee for the natural resources of the State and, as such we are not in an appropriate position to address human health issues. However, we would like to take this opportunity to make EPA aware of our concerns in two areas. The first issue deals with one component of the formula that was used to derive the human health criteria. Obviously, the human health criteria takes into account fish consumption rates, as well as what portion of the fish is consumed. The CTR indicates that the consumption rate utilized was 6.5 grams per day of fish tissue. This consumption rate, at least for the portion of the population that are subsistence fishermen, appears to be very low. If the human health criteria is to be adequately protective, this consumption rate should be revisited and a new rate developed to better protect these fishermen. Our second comment deals with the proposal to base criteria on fish tissue as opposed to water concentration. The DFG does not have a position with respect to this approach except to point out that compliance monitoring for fish tissue criteria may impact resources. This approach would mean an increased number of fish being collected for monitoring purposes which may impact fish resources. It may also impact the DFG's fiscal resources since we regulate scientific collection activity under which fish monitoring would fall.

Response to: CTR-026-007a

Regarding the fish consumption rate, see the response to this issue in CTR-002-002a. Regarding the comments on collecting fish for compliance monitoring and its impact on the Department of Fish and Game's (DFG) resources, the commenter has misunderstood EPA's reference to elevated fish tissue levels. The CTR criteria values are for ambient water quality criteria - that is, the numerical values represent water concentrations. EPA does not intend to add, through the CTR, the collection of fish for

monitoring purposes. Therefore, the DFG should not expect to have any additional workload for collecting or analyzing fish, nor should the DFG anticipate any loss to fisheries resources as a result of the CTR.

Comment ID: CTR-029-003
Comment Author: Center for Marine Conservation
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: The Center for Marine Conservation (CMC) is a nationwide, nonprofit advocacy group dedicated to the conservation and enhancement of coastal and ocean life and resources. CMC submits these comments on behalf of its 16,000 members in California and over 120,000 members nationwide.

CMC applauds EPA's efforts to bring California into compliance with the Clean Water Act 303(c)(2)(B). Implementing numeric criteria that will protect the beneficial uses of California's waters is of great importance to the health of coastal and marine ecosystems, and so to CMC and its members. The reliance in many areas of the state on narrative criteria threatens the health of most of the state's waters, thereby impacting both human health and the health of the state's economy that relies on clean water.

While CMC strongly supports the swift adoption of an Enclosed Bays and Estuaries Plan and an Inland Surface Waters Plan that contain numeric criteria for toxic pollutants, CMC also is concerned that many of the specific criteria contained in the proposed rule are weaker than those contained in published guidance. CMC also believes that the proposed rule can better protect certain subpopulations from harm caused by consumption of contaminated fish and shellfish. Finally, CMC is concerned that the economic analysis of the proposed rule over-emphasizes costs and under-reports the many benefits of improving water. quality throughout the state. These three points are reviewed below.

Fish Consumption Figures Should Be Recalculated to Protect Exposed Subpopulations Adequately

For purposes of establishing human health criteria, the proposed rule assumes the consumption of 6.5 grams of fish and shellfish per day by an average adult with a body weight of 70 kilograms.(*7) These two figures should be adjusted to better protect subpopulations exposed to contaminated fish and shellfish, particularly mercury contaminated fish and shellfish.

First, the 6.5 grams per day figure simply averages fish consumption over all of the population without accounting for the fact that much of the population either does not eat fish at all or relies on fish for much of their daily diet. A simple average thus underprotects much of the more significantly exposed population. Moreover, this figure is inconsistent with the Ocean Plan's estimate of 23 grams of fish and shellfish ingested per day. At a minimum, the analysis should be revised to use this more conservative figure.

Second, the use of a 70-kilogram man significantly underprotects children and pregnant women, who are most at risk from eating fish and shellfish contaminated with toxics. The proposed rule justifies this figure by claiming that "[p]ersons of smaller body weight are expected to ingest less ... so the dose per kilogram of body weight is generally expected to be roughly comparable." In fact, growing children and pregnant women often eat as much or more than many 70-kilogram adults, and so the calculated "safe" dose will be far too high for their body size. We urge EPA to base the human health criteria on a child 's weight in order to better protect this most vulnerable group of people.

(*7) Id. at 42176.

Response to: CTR-029-003

Regarding the protectiveness of the proposed criteria, see response to CTR-029-002a. With respect to EPA's estimation of costs and benefits, see response to CTR-029-004a.

EPA disagrees with the commenter that the fish consumption rate is based on "the fact that much of the population does not eat fish" - the opposite is true (see discussion on this same issue in the response to CTR-002-002a). Also, the commenter has advocated the use of 23 gm/day from the State of California's Ocean Plan estimate. This Plan, which is the State's undertaking, and the fish intake estimate is based on consumption relevant to marine species of fish and is, therefore, not an appropriate comparison to the estimate of 6.5 gm/day, which is based on fresh/estuarine species only. EPA acknowledges that there are population groups who consume greater amounts of fish than the overall population. However, EPA believes that its assumption of 6.5 gm/day is adequately protective. These issues are discussed in the response to CTR-002-002a. Regarding the body weight assumption, EPA believes that 70 kg is an appropriate body weight because it represents a reasonable measurement for adults and most of the criteria are based on chronic health effects [i.e., Reference Doses (RfDs) based on exposure over the course of a lifetime] for which the adult population is most appropriate. EPA acknowledges that where the RfD is based on health effects in children, the exposure parameters, including the body weight assumption, should be adjusted for a child. Such assumptions may be used on a chemical-by-chemical basis in calculating criteria. However, for this rule EPA believes it has made appropriate assumptions with the chemicals being regulated. For a specific discussion on this issue related to the mercury criterion, see the response to CTR-006-001a.

Comment ID: CTR-035-022
Comment Author: Tri-TAC/CASA
Document Type: Trade Org./Assoc.
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: p. 42176 & 42178 - Fish Consumption Rates In general, we support EPA's use of a fish consumption rate of 6.5 g/day in the CTR criteria. However, it may be more accurate to develop rates based on freshwater fish/shellfish consumption and marine/estuarine fish/shellfish consumption. While

EPA says on p. 42176 that the State may want to develop site-specific criteria where warranted, the Preamble also states on p. 42178 that EPA "supports the State's use of any appropriate higher state-specific fish and shellfish consumption rates in its readoption of criteria in its statewide plans." (emphasis added) We believe that the latter statement should be consistent with the previous statement, and that site-specific criteria should be developed using local fish and shellfish consumption rates where warranted, regardless of whether they are higher or lower than the national average consumption rate. For instance, in recalculating human health criteria for effluent dependent waters where fish consumption is a designated use, EPA or the State should consider using 1.72 g/day (see 62 Fed. Reg. 42179). We believe that this freshwater consumption rate may even be high, based on the following mean consumption rates of fish that are representative of California's freshwater fisheries (U.S. EPA, 1990b):

Bluegills 0.089 grams/day Carp 0.016 grams/day Catfish 0.292 grams/day Perch 0.062 grams/day Sunfish 0.020 grams/day Trout 0.294 grams/day

Response to: CTR-035-022

EPA disagrees that the two referenced statements regarding criteria development and fish intake rates are inconsistent. If a State determined, based on adequate data, that its population did in fact consume less fish than EPA's default value, EPA would support the State's use of that value. However, the commenter has presented values from only several species of fish from a much larger tabulated list in the original 1989 Exposure Factors Handbook (revised in 1995) and suggested that they are appropriate for a site-specific criterion. EPA disagrees with this rationale. The table actually presents consumption data from a study conducted for fish consumers in the United States. EPA believes that this is not necessarily representative of California-specific consumption patterns. The point of allowing such flexibility with site-specific criteria is that data are available for that particular site, which the commenter has not demonstrated. Further, EPA disagrees that the use of 1.72 gm/day would protect the general population of California. See additional discussion on protecting the general population in response to CTR-002-002a.

Comment ID: CTR-039-004
Comment Author: San Francisco BayKeeper
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/25/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: On behalf of San Francisco BayKeeper, its Stockton-based DeltaKeeper project, San Diego BayKeeper and Santa Monica BayKeeper (hereinafter "BayKeepeer"), I am submitting these comments for consideration in finalizing EPA's proposed rule establishing water quality criteria for priority toxic pollutants for the waters of the State of California. The need for numeric criteria for priority toxic pollutants was identified by Congress ten years ago when, in October, 1987, it enacted amendments to the Clean Water Act mandating that States issue such criteria by not later than October 18, 1990. The State of California adopted a portion of the mandated criteria in April, 1991, which, in large part, EPA approved. However, even that partial compliance was thwarted by the Sacramento Superior Court's

overly broad decision vacating the State's decision based solely on a flawed economic analysis purportedly required by State law.

Now, seven years later, although appreciative of the complexity of the task required by Congress, BayKeeper is deeply concerned that EPA's proposed rule to cure the State's violation will undermine permit limits promulgated throughout the Bay area and other regions, allowing more pollution to be discharged to San Francisco Bay and other state waters in violation of the State and EPA's antidegradation policies. BayKeeper also is very concerned that EPA is promulgating criteria for mercury, dioxin and 13 other pollutants which are based on drastic underestimates of the quantity of fish consumed by recreational and subsistence anglers throughout the State of California. BayKeeper also believes that at this late date, the proposal to allow compliance schedules which could delay for up to ten years compliance with permit effluent limitations based upon the proposed criteria is inappropriate given the already seven year delay suffered by California's aquatic ecosystems and the people who depend upon the health of those systems for food and recreation.

II. MANY RECREATIONAL AND SUBSISTENCE ANGLERS EAT MORE THAN 6.5 GRAMS OF FISH PER DAY.

According to EPA's "Economic Analysis of the Proposed California Water Quality Toxics Rule," (July 1997), anglers throughout the State who eat on average 107.1 grams/day of fish from California's waters (about 10% of the people fishing), after the proposed rule is enacted, will still be confronted with a lifetime cancer risk of from 6.65 x 10E-4 to 9.26 x 10E-4. Economic Analysis at 8-15. That correlates

roughly to a 1000 times greater chance of those anglers getting cancer than the 1 x E10-6 risk established by the State or an increased cancer risk of approximately I cancer death per 1,000 people. 107 grams is about a quarter of a pound. Surveys in the San Francisco Bay area have found that many anglers eat up to a pound (450 grams) per day of fish, increasing the risk even beyond that documented in the Economic Analysis. There is no reason to assume that subsistence anglers throughout the State are not consuming fish at a similar rate. In calculating criteria for mercury, dioxin, PCBs and other contaminants, EPA "assumes" a consumption rate of 6.5 grams per day. That number purports to be "equivalent to the average per-capita consumption rate of all (contaminated and non-contaminated) freshwater and estuarine fish and shellfish for the U.S. population." 62 Fed. Reg. at 42176. Congress' directive that the "solution to pollution is not dilution" should apply even more forcefully to human health impacts. EPA should not be allowed to dilute the health effects of fish consumption in California by averaging it into the fish consumption rates of the entire country nor should EPA dilute the effects of contaminated fish on those people who choose or need to use the Nation's waters more than others -- recreational and subsistence anglers -- by lumping their consumption rates in with the general populations.

Despite the fact that EPA has acknowledged in its Economic Analysis that it is well-documented that a significant subpopulation of people eat considerable amounts of fish, the proposed rule chooses to ignore this fact, couching it as a mere possibility which the State should address if it chooses to. See 62 Fed. Reg. 42176 ("[t]here may ... be circumstances where site specific numeric criteria are more stringent than the statewide criteria are necessary to adequately protect highly exposed subpopulations [like subsistence anglers'). Of course, the whole rationale for EPA to be issuing the proposed rule is inaction by the State of California. The notion that certain critical determinations involving direct human health impacts should be left to a crippled process is arbitrary and does not accomplish what Congress set out to do in establishing Section 303(c)(2)(B) back in 1987.

Perhaps the greatest irony of EPA's methodology in selecting a consumption rate is apparent if one considers that, as our waters become more and more deteriorated from toxic contaminants and people become more and more aware of that contamination, they are likely to eat less and less fish, driving down the national fish consumption average and, under EPA's way of calculating, allowing more pollution to be discharged. EPA must set a consumption level that protects the most sensitive users and renders California's waters truly "fishable" not "fishable if you want torisk getting cancer."

Response to: CTR-039-004

EPA believes its estimate of consumption level for the general population is reasonable and its selection of risk level for the general population affords adequate protection for all populations. For water quality criteria established in the CTR, individuals consuming 107.1 gm/day would be protected at approximately a 10^{-5} risk level and that individuals consuming up to a pound a day would still be protected at a 10^{-4} level. For a more detailed discussion on this same issue see the response to CTR-002-002a.

EPA acknowledges that the commenter drew its lifetime cancer risk estimates for people who eat an average of 107.1 gm/day of fish of 6.7×10^{-4} to 9.3×10^{-4} from the benefits portion of EPA's Economic Analysis (EA). However, the post rule cancer risk estimates in EPA's EA were calculated conservatively and are likely overstated for two reasons.

First, the benefits portion of the EA only accounts for risk reduction that occurs from reducing point source discharges. Thus, the post rule risk estimate in the EA is only a partial accounting of the potential reductions in fish contamination that will eventually result from implementation of the CTR. The reason for this is that EPA only accounted for costs of the rule to NPDES dischargers. In order to fairly compare costs with benefits, the benefits only included estimates of risk reductions that would take place due to increased controls on NPDES dischargers. However, in actuality, the standards established in the CTR apply to the waterbodies (i.e., inland

surface waters and enclosed bays and estuaries). As controls on other sources are implemented, perhaps as a matter of state law, (*e.g.*, remediation of contaminated sediments; best management practices to control non point sources and runoff from agricultural land), EPA expects that in the future the CTR criteria will be attained in the waterbodies and concentrations of pollutants in fish tissue will decline further.

Second, the baseline and post-regulatory risk estimate in the benefits portion of the EA was calculated by adding together all of the individual excess lifetime cancer risks for all of the chemicals identified in fish tissue data collected throughout the State. This assumes that an individual is eating fish contaminated with all of the chemicals identified in the study. To the extent that not all fish contain all contaminants at the assumed concentrations, both baseline and post-regulatory cancer risk estimates in the EA may be overstated. While this approach is appropriate for analytical purposes in the economic analysis' benefits assessment, agency scientists who establish ambient water quality criteria do not believe that the science demonstrates that individual risks can simply be added together for purposes of criteria development.

The commenter, in its discussion, also states that the consumption rate accounts for both contaminated and non-contaminated fresh/estuarine fish and shellfish. Although there are many circumstances relevant to fish consumption and contamination patterns, in an effort to be protective of populations that do consume most or all of their fish from a given water body, the equation to derive criteria does not subtract any of the consumption rate - that is, there is no discounting for non-contamination. This assumption helps to ensure that people can safely consume fish from waters designated for fishing and to derive allowable levels of toxics that are adequately protective of human health under the Clean Water Act.

EPA believes that its criteria are adequately protective. States have the flexibility to be more protective if they believe it is appropriate. However, with this rule, EPA is only promulgating criteria. That is, antidegradation policies are not affected by this action. Regulated entities must still comply with existing State antidegradation policies and procedures. Also, compliance schedules are a fact-specific, facility-specific determination. All stakeholders will have an opportunity to review the facts and comment on the appropriateness of a compliance schedule for any given situation as part of the public noticing of the draft NPDES permit. With respect to the comments regarding the length of the compliance schedule, see response to comment CTR-002-010b.

Comment ID: CTR-060-015
Comment Author: San Diego Gas and Electric
Document Type: Electric Utility
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: PROVISIONS SDG&E DOES NOT SUPPORT

As described in the following comments SDG&E does not support the following provisions:

* The fish consumption rate of 6.5 g/day used is not representative of fish consumption within the State of California, and overestimates exposure. This value is reported by the EPA to represent an estimate of average consumption of fish and shellfish from estuarine and fresh waters by the U.S. population(*3) . The draft EPA

Exposure Factors Handbook (*4)(EFH) summarizes studies on the intake of fish and shellfish, and includes study results for Northern and Southern California from the National Marine Fisheries Service. While this data is compiled for fish from marine habitats, other data summarized in Table 10-8 of the draft EFH suggests that the percentage of the population consuming and the mean daily fish intakes are higher for fish from marine habitats than for freshwater/estuarine habitats. The mean daily intake of marine finfish for anglers was 2.0 g/day for both Northern and Southern California, and the intake was 0.2 or 0.3 g/day on a per capita basis in the coastal population. The value of 2.0 g/day would be a more reasonable consumption rate and should be sufficiently health-protective of the more highly exposed sub-population of the state, because this intake is restricted to the angler population, which may reasonably be expected to consume their own catch and to represent a greater exposed population than the entire population of the state. The intake rate from this database is more up-to-date and is geographically representative. The criteria should be recalculated using the California fish intake rate.

General human health criteria issues

* Fish consumption rate - See the above discussion for PAHs regarding the over estimation of fish consumption rates used in the human health criteria.

(*3) U.S. EPA, 1989. Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish. Office of Water Regulations and Standards. EPA-503/8-89-002.

(*4)U.S. EPA, 1996. Exposure Factors Handbook. EPA/600/P-95/002Ba. Office of Research and Development.

Response to: CTR-060-015

EPA disagrees with the commenter. EPA believes that the 6.5 grams/day fish intake estimate is adequately protective of the general population of fish consumers over the course of a lifetime and is appropriate for this rule. The commenter suggests that EPA use an intake value based on marine finfish consumption of 2.0 gm/day. However, it is the fresh/estuarine species of finfish and shellfish that apply to the development of water quality criteria for the waters covered under this rule. Specifically, EPA's ambient water quality criteria are applicable to inland waters and estuaries. Further, EPA is aware of other studies that indicate higher consumption rates than suggested by the commenter. For further discussion on the basis of EPA's estimate, refer to the response for CTR-002-002a.

Comment ID: CTR-065-003a
Comment Author: Environmental Health Coalition
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 09/26/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-21

Comment: HUMAN HEALTH CRITERIA

EHC is very concerned about the use of 6.5 grams per day of fish tissue as a basis upon which to derive human health criteria. This is not adequate to protect the many thousands of subsistence fishers of California coastal waters. We trust EPA is not in the business of protecting "most of the people, most of the time" as is the indicated goal for marine organisms elsewhere in the CTR (see comments below).

We refer you to a study conducted by the Save San Francisco Bay Association that concluded that fishers of San Francisco Bay consumed 81grams per day in the week prior to the survey with consumption rates as high as 450 grams/day... This element of the CTR must be recalculated at a higher rate of consumption and with a healthy safety margin to accommodate for synergistic and cumulative effects. Further, the Save San Francisco study showed that heads and skin were frequently consumed, the health criteria must reflect these actual eating patterns and practices as well and reflect the cultural diversity of users of the Bays. Since many subsistence fishers are people of color, adoption of this rule could violate the President's Order on Environmental Justice b exposing these populations to increased and undue environmental health risks.

Response to: CTR-065-003a

EPA acknowledges that there are population groups that consume greater amounts of fish than the overall population. However, EPA believes that the intake rate of 6.5 grams/day is adequately protective of the general population of fish consumers over the course of a lifetime. EPA has reviewed the materials submitted by the commenter from the Save San Francisco Bay Association and, as is discussed in CTR-002-002a, the commenter needs to separate out those species defined as marine from the referenced tables (e.g., shark, ray, cod, halibut, mackerel, marine salmon) in order to appropriately compare fish intake rates that are relevant to the development of the CTR criteria. Other issues on the fish consumption rate are also discussed in the response to CTR-002-002a. Regarding the comment on the President's Executive Order on Environmental Justice, see the response to CTR-002-005a.

Comment ID: CTR-095-001d
Comment Author: M. Ruth Uiswander
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-20
C-17a
C-21

Comment: In regard to the numeric water quality standards criteria for California surface water, they have been revealed by environmental groups to be insufficiently protective and environmentally unjust. The proposed new rules assume fish ingestion of 6.5 grams per day. In reality, consumption of fish in some communities can be as high as 1 pound per day. This level of consumption is especially likely among subsistence fishers.

Please prevent toxic pollution in California's bays by making more protective standards that consider all toxic pollutants and consider the fish consumption habits of subsistence anglers.

Response to: CTR-095-001d

See responses to CTR-002-002a, CTR-002-005a and the response to CTR-058-001 (Subject Matter Code C-13, Risk Level).

Comment ID: CTR-097-001b
Comment Author: Mark Shaw
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-17a

Comment: I am writing to urge you to more stringent - and more protective - water quality standards for California surface water. The proposed standards are too weak and discriminatory in their effects.

Lastly, the proposed standards are discriminatory in their effects in that they assume consumption of only 6.5 grams of fish per day per person. Many poorer communties catch and eat fish for subsistence - as much as a pound per day per person (more than sixty what the EPA estimates!) placing them at greater risk. The standards should be set to protect everybody, including those who happen to be poor and/or eat a significant amount of fish.

Please set the standards to protect us all and move us closer to the goals of the Clean Water Act, that our waters be safely fishable and swimmable.

Response to: CTR-097-001b

See responses to CTR-002-002a, CTR-002-005a and the response for Subject Matter Code C-13, Risk Level.

Comment ID: CTR-098-001
Comment Author: Elena Goldstein
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/02/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: I am writing to urge you to work towards the prevention of toxic pollution in the bavs of California. It is evident that more protectiive standards are needed to protect those who fish and those who consume the

fish. Not to do so would be completely irresponsible. Turning a deaf ear to the situation or bending to pressure from business interests would, I suggest, also be immoral.

Response to: CTR-098-001

See responses to CTR-002-002a and CTR-002-005a.

Comment ID: CTR-099-002
Comment Author: Emil A. Lawton, Ph.D.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/03/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: First, the 6.5 grams per day must be out in left field. Your staff must have divided the total consumption by the population. It ignored that some people do not eat fish, some eat very little and others eat fish regularly. Subsistence fishers are the obvious case in point, but what about so many of us who have eschewed red meat for a contemporary healthy diet of fish and fowl. We eat about I/3 LB three times a week. This comes to about 61 grams a day, almost an order of magnitude larger than you baseline case.

Response to: CTR-099-002

EPA acknowledges that there are population groups that consume greater amounts of fish than the overall population. However, EPA believes that the intake rate of 6.5 grams/day is adequately protective of the general population of fish consumers over the course of a lifetime. For a more detailed discussion on this issue, see response to CTR-002-002a.

Comment ID: CTR-101-001a
Comment Author: Cheesemans' Ecology/Brd Safari
Document Type: Environmental Group
State of Origin: CA
Represented Org:
Document Date: 10/06/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-20

Comment: We would like to thank the EPA for accepting comments on its proposed numeric water quality standards criteria for California surface water. We urge the prevention of toxic pollution in California's bays by creating more protective standards that consider all toxic pollutants of concern and that address the consumption habits of subsistence fishers, as well as "average" fish consumers.

Response to: CTR-101-001a

Regarding fish consumption, refer to the response to CTR-002-002a.

Comment ID: CTR-102-002
Comment Author: Bryan Gordon
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/10/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: California EPA should not be satisfied that our state's water quality standards are adequate if they only protect the segment of the population that does not have regular or frequent contact with the water or aquatic organisms. Water quality standards should ensure that the state's waterways are pure enough to protect that segment of the population that includes subsistence fish consumers.

Since the Clean Water Act has the goal of making our Nation's waterways "fishable and "swimable", any water quality standards that do not protect the health of that segment of the population that consumes more fish than the prescribed 6.5 grams per day is simply flawed.

Response to: CTR-102-002

See response to CTR-002-002a.

Comment ID: CTR-104-001
Comment Author: Lucy Nelson, et. al.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/15/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: It has been proven that unacceptable amounts of such toxins as mercury, cioxin and 13 other pollutants are in our state's surface waters. In establishing standards for these toxins, proposed new rules assume fish consumption at 6.5 grams per day. But in certain communities where subsistence anglers eat fish more often, it can amount to one pound daily. Even at 1/4 pound daily, the proposed standards would mean a cancer risk 1000 times higher than current state law states as "acceptable".

We should address the consumption habits of subsistence fishers, as well as the average fish consumer from the general public.

Thank you for your immediate attention to the above.

Response to: CTR-104-001

EPA disagrees with the commenter that persons consuming a quarter pound of fish per day would experience a cancer risk 1,000 times higher than the basis of the CTR. EPA believes that individuals consuming this amount would be protected at approximately a 10-5 risk level and that idividuals consuming up to a pound a day would still be protected at a 10-4 risk level. For a more detailed discussion on this issue, see response to CTR-002-002a.

Comment ID: CTR-104-002b
Comment Author: Lucy Nelson, et. al.
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/15/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-01a

Comment: Proposed mercury standards fail to account for bioaccumulation of mercury in fish tissue. Mercury is amassed through their consumption of food.

Response to: CTR-104-002b

Regarding the issue on mercury bioaccumulation, see response to CTR-002-007b.

Comment ID: CTR-105-001b
Comment Author: Heather Catherine Park Tausig
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/13/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-20

Comment: I understand that the EPA is currently accepting comments on its proposed numeric water quality standards criteria for California surface water. I am writing to urge the EPA support the prevention of toxic pollution in California's bays by creating more protective standards that consider all toxic pollutants of concern and that address the consumption habits of subsistence fishers, as well as "average" fish consumers.

Response to: CTR-105-001b

Regarding the fish consumption issue, refer to response to CTR-002-002a.

Comment ID: CTR-106-001
Comment Author: Robert Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/28/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: It has been proven that unacceptable amounts of such toxins as mercury, cioxin and 13 other pollutants are in our state's surface waters. In establishing standards for these toxins, proposed new rules assume fish consumption at 6.5 grams per day. But in certain communities where subsistence anglers eat fish more often, it can amount to one pound daily. Even at 1/4 pound daily, the proposed standards would mean a cancer risk 1000 times higher than current state law states as "acceptable".

We should address the consumption habits of subsistence fishers, as well as the average fish consumer from the general public.

Thank you for your immediate attention to the above.

Response to: CTR-106-001

See response to CTR-104-001.

Comment ID: CTR-106-002b
Comment Author: Robert Brown
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 10/28/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-01a

Comment: Proposed mercury standards fail to account for bioaccumulation of mercury in fish tissue. Mercury is amassed through their consumption of food.

Response to: CTR-106-002b

Regarding the issue on mercury bioaccumulation, see response to CTR-002-007b.

Comment ID: CTR-109-001a
Comment Author: Maggie Miller
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/01/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-20

Comment: The new water quality standards the EPA is proposing for California surface waters disturbs me greatly. There are several problems with the proposed rules. First in establishing standards for mercury, dioxin, PCBs, and other contaminants, the proposed new rules assume fish consumption at 6.5 grams per day yet consumption of fish in certain communities can be as high as one pound per day, over 60 times more than estimated by the EPA. Please don't underestimate fish consumption by people of different races and cultures.

Please prevent the toxic pollution of California waters by creating more protective standards that consider all toxic pollutants and all consumers of fish. Thank you.

Response to: CTR-109-001a

EPA acknowledges that there are population groups that consume greater amounts of fish than the overall population. However, EPA believes that the intake rate of 6.5 grams/day is adequately protective of the general population of fish consumers over the course of a lifetime. For a more detailed discussion on this issue, see responses to CTR-002-002a and CTR-002-005a.

Comment ID: CTR-109-002b
Comment Author: Maggie Miller
Document Type: Citizen
State of Origin: CA
Represented Org:
Document Date: 12/01/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-01a

Comment: Second, the proposed mercury standards fall to account for the bioaccumulation of mercury in fish tissue. The proposed standard ignores mercury that enters fish through their own consumption of food.

Response to: CTR-109-002b

Regarding the issue on mercury bioaccumulation, see response to CTR-002-007b.

Comment ID: CTRH-001-050b
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES C-1a

Comment: For mercury, certainly I would concur with the previous comments, that the number should be -- that is appropriate is accumulation factors.

Now the bioconcentration factor, in deference to this state's consumption rates that have been determined are appropriate for California, I think using the average consumption rate for everyone in the country, by definition, lops off about half of the population. It seems to me that it doesn't account for those users of the bay who are the high consumption -- high fish-consumption users, which obviously there's a number of them, and that's not reflected in that average at all.

So I think that those bioaccumulation factors are important to the mercury number base data that we have for the bay for all the reasons stated earlier, and similarly for dioxin. It seems as if EPA would like to back away on that, the criteria that is listed.

Response to: CTRH-001-050b

Regarding the issue on the fish consumption rate, see response to CTR-002-002a. Regarding the issue on mercury bioaccumulation, see response to CTR-002-007b.

Comment ID: CTRH-001-053
Comment Author: Michael Lozeau
Document Type: Public Hearing
State of Origin: CA
Represented Org: S.F. Bay/Delta Keeper
Document Date: 09/17/97
Subject Matter Code: C-14 Fish or Water Consumption
References:
Attachments? N
CROSS REFERENCES

Comment: I already mentioned average consumption rate, but 6.5 grams is just not realistic. I have people out fishing every day at -- my office is on the end of a pier in San Francisco, and every day there are at least five or six people fishing off that pier, the same people every day, and some of them are great at it. They throw that line in and get six or seven fish every day, and I'm sure they're eating them.

I can't actually communicate with them very well -- one of them, I can. And people who eat a lot of fish, consuming fish regularly from the bay, 6.5 is really not a realistic number to protect the most sensitive part of the population.

And EPA is doing air rules related to asthma, geared for the most sensitive part of the population, but you get to the water rules and we're looking at very little -- the average for the whole country, even including Montana or Idaho, where -- I don't even know whether fish consumption goes down in the middle of the country, but I have to imagine that in the coastal states it's much higher.

So the average has nothing to do with the most sensitive population. so that should be taken into account. That would adjust some numbers pretty drastically.

Response to: CTRH-001-053

See responses to CTR-002-002a and CTR-002-005a.